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(71) Applicant *(for all designated States except US)*: **SINTEA BIOTECH S.P.A.** [IT/IT]; Via Aquileia, 33/H, I-20021 Baranzate (Milano) (IT).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **SALA, Giuseppe** [IT/IT]; Via Trezzi, 5, I-20033 Desio (Milano) (IT). **GUERRA, Paolo** [IT/IT]; Via Tiziano, 20, I-20145 Milano (IT). **CASERTA, Piergiorgio** [IT/IT]; C.so di Porta Vigentina, 21, I-20122 MILANO (IT).

(74) Agents: **VITTORANGELI, Lucia** et al.; Jacobacci & Partners S.p.A, Via Senato, 8, I-20121 Milano (IT).

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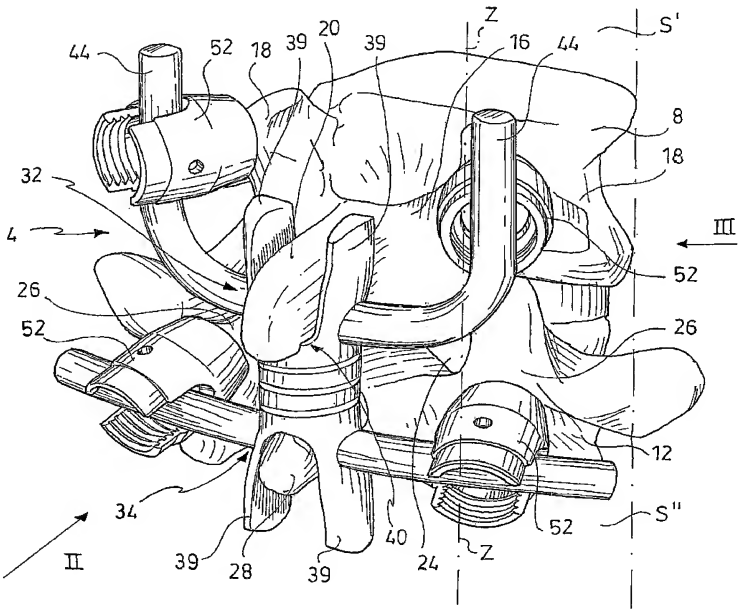
(54) Title: DEVICE, KIT AND METHOD FOR INTERVERTEBRAL STABILIZATION



(57) Abstract: An intervertebral stabilizing device adapted to stabilize two or more vertebral bodies one another. The device comprises two fastening elements adapted to be associated to two vertebral bodies being contiguous to each other and a junction element operatively connecting the two fastening elements. The fastening elements and the junction element gradually distribute the stresses both on the peduncles and the spinous bones of the adjacent vertebrae, so as to gradually and continuously stress the column length, thus avoiding sudden changes in load and stiffness in the borderline zones.

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DESCRIPTION

"DEVICE, KIT AND METHOD FOR INTERVERTEBRAL STABILIZATION"

[0001] The present invention relates to a device for the intervertebral dynamic stabilization, adapted to correct the excessive mobility between two or more vertebrae while maintaining the normal gap between the latter. The present invention also relates to a medical kit for the intervertebral stabilization and an intervertebral stabilization method.

[0002] Different devices are known to dynamically stabilize two or more vertebrae between one another.

[0003] Some of these devices are of the 'interspinous' type, i.e. they comprise a pair of saddles, each to be ridingly associated to a spinous bone of two adjacent vertebral bodies; the saddles are associated to a same elastic body allowing relative motions between the vertebrae.

[0004] However, these devices considerably urge the spinous bones which are substantially cantilever stressed small-size beams. Therefore, there is the risk that the spinous bones may break.

[0005] On the other hand, other devices comprise peduncular beams or bars which are fastened to the peduncles of at least two adjacent vertebral bodies by

means either of screws or bushes. These screws can be manufactured either as one piece or in several pieces, being elastically connected to one another. It has been seen that these devices have the fault in considerably stiffening the vertebral bodies being made integral to each other so as to cause a sudden stress discontinuity at the so-called 'borderline zones', i.e. the borderline areas on the unfastened vertebral bodies. Thereby, a fast degeneration of the sound vertebral bodies, being adjacent to the vertebral bodies fastened to each other by means of the same devices is caused.

[0006] The problem of the present invention is to provide a device for dynamic stabilization which solves the drawbacks mentioned with reference to the prior art.

[0007] These drawbacks and limitations are solved by a device for intervertebral dynamic stabilization in accordance with claim 1.

[0008] Other embodiments of the device according to the invention are described in the subsequent claims.

[0009] Further characteristics and the advantages of the present invention will be better understood from the description of preferred and non-limiting exemplary embodiments thereof as set for herein below, in which:

[0010] Fig. 1 shows a perspective view of a device for the intervertebral dynamic stabilization according to

the present invention, in an assembly configuration between at least two vertebral bodies;

[0011] Fig. 2 shows a view of the device from Fig. 1, taken from the side of arrow II from Fig. 1;

[0012] Fig. 3 shows a view of the device from Fig. 1, taken from the side of arrow III from Fig. 1;

[0013] Fig. 4 shows a perspective view of a device for the intervertebral dynamic stabilization according to a further embodiment of the present invention, in an assembly configuration between at least two vertebral bodies;

[0014] Fig. 5 shows a view of the device from Fig. 4, taken from the side of arrow V from Fig. 4;

[0015] Fig. 6 shows a view of the device from Fig. 4, taken from the side of arrow VI from Fig. 4;

[0016] Fig. 7 shows a perspective view of a device for the intervertebral dynamic stabilization according to a further embodiment of the present invention, in an assembly configuration between at least two vertebral bodies;

[0017] Fig. 8 shows a view of the device from Fig. 7, taken from the side of arrow VIII from Fig. 7;

[0018] Fig. 9 shows a view of the device from Fig. 7, taken from the side of arrow IX from Fig. 7;

[0019] Figs. 10 and 11 show a perspective view and a

sectional view, respectively, of a device according to the present invention;

[0020] Figs. 10A and 11A show enlarged details from Figs. 10 and 11, respectively;

[0021] Figs. 12A, 12B and 13A-13E show perspective views of further embodiments of devices for the intervertebral dynamic stabilization according to the present invention;

[0022] Figs. 14A and 14B show perspective views of assembly elements of a device according to the present invention;

[0023] Figs. 15, 16, 17A, 17B, 18 show inserting steps of a device for the intervertebral dynamic stabilization according to the present invention;

[0024] Figs. 19A-19C show diagrams of compression, flexural and torsional stiffness, respectively, of a device according to the present invention compared to the prior art devices.

[0025] The elements or element parts in common among the embodiments described herein below will be indicated with the same reference numbers.

[0026] With reference to said figures, a device for intervertebral dynamic stabilization, adapted to be interposed between at least one first and one second vertebrae 8,12 being adjacent to each other, for example

a cranial vertebra and a caudal vertebra, respectively, identifying an extending direction Z of the backbone length has been generically indicated with 4.

[0027] The first vertebra 8 comprises a first vertebral body 16 and a first pair of peduncles 18, being arranged on opposite sides relative to an anterior-posterior symmetry plane S' of the same vertebra. The first vertebral body 16 comprises a first spinous bone 20, symmetrically arranged relative to said symmetry plane S'.

[0028] The second vertebra 12 comprises a second vertebral body 24 and a second pair of peduncles 26, being arranged on opposite sides relative to an anterior-posterior symmetry plane S" of the same vertebra, preferably coincident with the symmetry plane S' of the first vertebra 8.

[0029] The second vertebral body 24 comprises a second spinous bone 28, symmetrically arranged relative to said symmetry plane S".

[0030] The device 4 comprises a first and a second fastening elements 32,34 adapted to be fastened to the upper and lower vertebrae 8,12, respectively.

[0031] According to an embodiment, the first fastening element 32 comprises a first coupling portion 38, adapted to be abutted on the first spinous bone 20.

Preferably, said first coupling portion 38 has either a saddle or a 'U' configuration, comprising two branches 39, having incident portions, at a first groove 40 of the 'U' shape, and portions which are parallel to one another, at the 'U' arms. Thereby, the first coupling portion 38 may be fitted on the first spinous bone 20, for example according to a shape coupling, thus bringing the first groove 40 in abutment against the first spinous bone 20. In an assembly configuration, the bottom of the first groove faces the second vertebra 12, i.e. the branches 39 converge on the second vertebra 12.

[0032] The first groove 40 of said support portion has advantageously a thickness nearly equal to the spinal bone thickness, the thicknesses being measured relative to a direction which is perpendicular to the symmetry plane, so as to provide a shape coupling between the first groove 40 and the first spinous bone 20.

[0033] A first pair of fixing bars 44, preferably symmetrically arranged relative to the first coupling portion 38, branches from the first coupling portion 38 of the first fastening element 32.

[0034] Said first fixing bars 44 have for example a circular section and are curved so as to take a direction which is substantially parallel to the symmetry plane S' of the first vertebra 8 and so as to

intercept at least the first pair of peduncles 18.

[0035] Advantageously, the fixing bars 44 and the first coupling portion 38 are fastened to each other so that the stresses transmitted to the first fastening element are distributed both on the first spinous bone and on the first pair of peduncles.

[0036] Advantageously, the cross extension of the first pair of fixing bars 44 is such to intercept the opposite peduncles of the same vertebra; with cross extension is meant either the arm distance or length relative to a direction which is parallel to the symmetry plane S' of the first vertebra 8.

[0037] Said first fixing bars 44 have for example a circular section and are for example oriented so that, on a plane perpendicular to the symmetry plane S', are either angled or incident, by a first incidence angle α' relative to Z-axis of the column length identified by the vertebrae. In other words, the fixing bars 44 are oriented so as to intercept the first pair of peduncles 18, so as to adjust the device 4 to the column length anatomy. The first incidence angle α' ranges between 0 and 20 degrees and is preferably equal to 12 degrees.

[0038] Advantageously, the first fastening element 32 comprises a plurality of fastening screws 50, adapted to firmly fasten the latter to the vertebral bodies and

particularly to the peduncles 18 of the first vertebra 8 and/or the vertebrae being adjacent to the first vertebra 8 on the opposite side of the second vertebra 12.

[0039] The fastening screws 50 comprise a bush 52, for example of a cylindrical shape and provided with a cavity 53. The cavity 53 is defined by an abutment 54 provided with a through hole 56, so as to have a circular ring shape as a whole. The abutment 54 is adapted to provide an end-of-stroke to the screwing of the screw into the bone.

[0040] Preferably, a retainer 58 provided with a circular milling 60 adapted to be abutted by a portion of said fixing bars 44 is housed within the cavity 53. The head 61 is also provided with a housing 62, for example of a prismatic hexagonal shape, in order to allow the screw to be screwed by means for example of an Allen wrench. The retainer 58 is advantageously provided with a pair of pockets 63, being diametrically opposite to each other. In an assembly configuration, the screw is inserted into the cavity 53 of the bush 52, thus bringing the head 61 in contact with the abutment 54. The retainer 58 is then inserted into the cavity 53, in contact with the head 61. Preferably, the bush 52 is provided with holes 63' being diametrically opposite to

one another along the side surface of the bush. Preferably, said holes 63' are caulked so that this caulking also partially occupies the pockets 63. The caulking penetration into the pockets 63 ensures the axial locking of the head 61 between the abutment 54 and the retainer 58. The retainer 58 is provided with the through hole 56 in order to allow the screw head to have access to the housing 62 from the outside, i.e. from the side of the cavity 53 of the bush 52.

[0041] The fastening screw 50 is preferably of the self-tapping type so as to be capable of being directly screwed into the bone.

[0042] The bush 52 has a notch 64 extending throughout a diameter of the bush 52 and has a thickness which is not lower than the thickness of the bars, so as to allow the bars to be inserted thereinto.

[0043] The bush has an inner threading 66, being at least partially interrupted by the notch 64, on the opposite side of the through hole 56 of the retainer 58.

[0044] The screws 50 comprise a cap 68 of a cylindrical shape and provided with a threading 69 on the side surface thereof so as to be capable of being screwed onto the bush 52 after the fixing bars have been coupled therewith. Thereby, the cavities 53 of the bushes 52 are closed. The cap comprises for example a clamping hole 69

for inserting a wrench thereinto, for example either of the hexagonal type or the 'torx' type, in order to allow the same to be screwed.

[0045] According to an embodiment, the second fastening element 34 comprises a second coupling portion 72, adapted to be abutted against the second spinous bone 28. Preferably, said second coupling portion 72 has either a saddle or a 'U' configuration, comprising two branches 74, having incident portions, at a second groove 76 of the 'U' shape, and portions which are parallel to one another, at the 'U' arms. Thereby, the second coupling portion 72 may be fitted on the second spinous bone 28, for example according to a shape coupling, thus bringing the second groove 76 in abutment against the second spinous bone 28.

[0046] In an assembly configuration, the bottom of the second groove faces the first vertebra 8, i.e. the branches 74 converge on the first vertebra 8.

[0047] The second groove 76 of said support portion has advantageously a thickness nearly equal to the thickness of the second spinous bone, the thickness being measured relative to a direction which is perpendicular to the symmetry plane, so as to provide a shape coupling between the second groove 76 and the second spinous bone 28.

[0048] According to a possible embodiment, such as shown for example in Fig. 12A, at least one of said fastening elements, for example the second fastening element 34, is free of fixing bars, and the positioning and anchoring of the same to its respective vertebral body is ensured by the shape coupling between the second groove 76 and its respective spinous bone 28.

[0049] According to possible further embodiments, the anchoring between the spinous bones 20,28 and coupling portions 38,72 can be also ensured by means of small strings, passing around the spinous bones 20,28 and through suitable coupling holes provided on the branches 39,74. According to a further variant, the coupling portions can be fastened to the spinous bones by means of dowels 79 passing through the branches 39,74 and the spinous bones 20,28.

[0050] According to an advantageous embodiment, a second pair of fixing bars 80, preferably symmetrically arranged relative to the symmetry plane S" of the second coupling element branches from the coupling portion of the second coupling element.

[0051] Said fixing bars 80 have for example a circular section and are for example oriented so that, on a plane which is perpendicular to the symmetry plane S", are either angled or incident, of a second incidence angle

α" relative to the symmetry plane S". In other words, the fixing bars 80 are oriented so as to intercept the second pair of peduncles 26 which are in a backer position relative to the spinous bone, so as to adjust the device 4 to the column length anatomy. This incidence angle α" ranges between 0 and 20 degrees and is preferably equal to 12 degrees.

[0052] Advantageously, the fixing bars 80 and the second coupling portion 72 are fastened to each other so that the stresses transmitted to the second fastening element 34 are distributed both on the second spinous bone 28 and the second pair of peduncles 26.

[0053] Advantageously, the second coupling element also comprises a plurality of fastening screws 50, adapted to firmly fasten the latter to the vertebral bodies and particularly to the second vertebra 12.

[0054] Advantageously, the arm cross extension is such to intercept the opposite peduncles of the same vertebra; with cross extension is meant either the arm distance or length relative to a direction which is perpendicular to the symmetry plane.

[0055] The first and second fastening elements 32,34 are operatively connected to each other by means of a junction element 84, adapted to allow a relative rotary, translatory and flexural motion between the latter.

[0056] The junction element 84, according to an embodiment, as illustrated for example in Figs. 10-12A, comprises a cylindrical body 86 provided with a plurality of notches 88, being arranged along the circumference of the latter. Said notches 88 have a radial depth which is lower than the radius of the cylindrical body 86, so as to provide a type of helical spring, provided with turns 90 for example of a helical shape.

[0057] Preferably, the cylindrical body is provided with a single notch helically arranged so as to provide a single continuous spiral.

[0058] The cylindrical body 86 is capable of allowing flexural motions between the first and second fastening elements 32,34 and hence between the vertebral bodies to which said fastening elements are associated, due either to the notches 88, or preferably to the single continuous notch. The stop for said relative motions is provided either by the abutment or pack closing condition of the element turns. Moreover, due to the notches, the element allows torsional motions relative to a rotation axis which is also a X-symmetry axis of the cylindrical body 86.

[0059] In order to allow a better flexibility of the junction element, the cylindrical body is provided with

a central cylindrical hole 91. According to an embodiment, the central cylindrical hole 91 has a diameter which is equal to about 1/3 of the outer diameter of the cylindrical body.

[0060] The junction element 84 is preferably made as one piece, starting from a metallic cylindrical body being initially solid and then subjected to a processing step for example by means of electron discharge machining. According to further embodiments, the junction element may be obtained either by casting or by a machine-tool processing, preferably of the CNC-type.

[0061] The intervertebral stabilizing device 4 can be either totally or partially manufactured in titanium alloy, other types of metals or polymeric materials. For example, the junction element 84 can be manufactured in a different material compared to the connecting bars 44,80.

[0062] The ends of said element are advantageously integral to their respective fastening elements 32,34.

[0063] According to further embodiments of the present invention, such as shown for example in Figs. 12B and 13, the junction element 84 can be provided by means of a joint of the ball type 92, adapted to allow relative rotary motions between the same elements. The joint of the ball type may also comprise a spring elastic element

therein, so as to dampen the relative motion between the fastening elements 32,34 and also allow translatory axial motions along the extending direction of the vertebral column length involved.

[0064] According to a further embodiment, as illustrated for example in Fig. 13A, the junction element 84 may comprise a cylindrical body 86 containing a damper 96 therein, for example in polymeric material, optionally filled with saline therein.

[0065] The device according to the present invention may comprise various variant embodiments. For example, only one of the fastening elements can be provided with fixing bars, such as illustrated for example in Fig. 12A. The fixing bars can be both transversally and axially oriented, both at the first 32 and second 34 fastening elements. Furthermore, as illustrated in Figs. 7 and 8, both the fastening elements may comprise bars which are longitudinally arranged on the side of their respective branches 39.

[0066] Moreover, the connecting bars can be extended so as to involve a plurality of vertebral bodies; for example, the bars of the first vertebra may intercept two or more vertebrae being adjacent to the first vertebra on the opposite side of the second vertebra, so as to stabilize a column length comprising three or more

vertebrae being consecutive to one another.

[0067] The connecting bars, such as shown for example in Fig. 13B, may comprise flexible elements 97 similar to the junction element 84, preferably comprising a cylindrical body provided with a continuous helical groove and a central hole so as to ensure further flexibility to the connecting bars, as well as a better adjustment of the connecting bars to the column length morphology.

[0068] Advantageously, the device according to the present invention is implanted by using some tools.

[0069] As shown for example in Figs. 15-18, there is provided a template tool 98 comprising a first and second measuring elements 100,102 each adapted to be interfaced with the spinous bones 20,28 of the two adjacent vertebral bodies 8,12.

[0070] In fact, each of said measuring elements 100,102 comprises a saddle portion 104, adapted to be fitted on its respective spinous bone, and a pair of slotted links or arms 106, being symmetrically arranged relative to said saddle portion 104, so as to intercept the peduncles of their respective vertebral bodies.

[0071] Each slotted link 106 is provided with a groove 108, adapted to allow either a point of a punch 110 or of a marking tool to pass through. The punch can be

provided with a point adapted to scratch the cortex of the vertebral body at the peduncles. The marking tool can be provided for example with a point adapted to mark with a dot, being for example coloured, the cortex of the vertebral body at the peduncles.

[0072] The two measuring elements 100,102 can be axially adjusted to each other, along a mutual extension axis by means of a screwdriver 112. Preferably, a graduated scale is inserted at the connecting portion between the two measuring elements 100,102, in order to provide a direct measuring of the size of the device that best suits the column length.

[0073] A further tool for inserting the device is represented by a gripper 114 having a pair of grip means 116,118. The grip means 116,118 are slidingly associated to each other at a first end 120 by the interposition of a pivot 122, whereas, at a second end 124 opposite to said first end 120, each is provided with a pair of tines 126 adapted to grasp the device at the junction element 84.

[0074] The gripper 114 is provided with a gauged screw 130 adapted to adjust the axial distance between the two grip elements 116,118 which can relatively slide on each other along the pivot 122 in common, at a central portion 128, included between said ends 120,124.

[0075] The gripper 114 allows the device 4 to be grasped from the side of the junction element by locking the tines 126 between the junction element and the fixing bars 44,80.

[0076] The technique for inserting the device according to the invention will be now described herein below.

[0077] Particularly, the device 4 is preferably pre-assembled, i.e. the fastening elements 32,34 and the junction element are already pre-assembled to each other so as to form a single device 4.

[0078] The pre-assembly can be preferred both in the embodiment with a spring junction element 84, and in the embodiments with a joint either of the ball or damping type.

[0079] Advantageously, before proceeding with the device insertion, the template tool 98 is used by approaching this tool to the column length to be stabilized.

[0080] The template tool 98 is firstly fitted on the spinous bones of the vertebrae to be stabilized, thus bringing the saddle portions 104 in contact with the spinous bones; then, the axial position between the two measuring elements 100,102 is adjusted.

[0081] The marking of the vertebra peduncles on which the device 4 will have to be subsequently fastened is then carried out. The marking can be carried out with the aid

either of a drift 110 or a marker, by inserting the latter through the grooves 108 provided on the slotted links 106.

[0082] The template tool 98 which can thus provide the indication of the size of the device to be implanted is then removed. With dimension or size is meant the distance between the two grooves 40 and 76 in a resting configuration of the junction element 84. Thereby, it is possible to select the device 4 with the size which is more easily adapted to the morphology of the column length to be stabilized.

[0083] The screw positioning on the peduncles and the screw screwing onto the peduncles are carried out at the markings so as to lock the bushes in position. After the screws have been screwed, the bushes may advantageously rotate relative to the peduncles, so as to orientate the notches 64 of the bushes parallel to the final arrangement which the connecting bars of the fastening devices will have to take; for example, longitudinally in the case of the first locking element and transversally in the case of the second locking element.

[0084] Therefore, with the aid of the gripper 114, the device 4 is grasped and positioned near the vertebrae to be connected, by inserting the bars of the first and second fastening elements 32,34 into their respective

notches of the bushes already fastened to the peduncles. Particularly, the connecting bars are placed in abutment on the millings 60 of the retainers 58. The device grasping with the gripper, as illustrated in Fig. 17A, may be performed by locking the tines 126 between the coupling portions 38,72 and their respective fixing bars 44,80, so as to allow the junction element to be compressed in order to position the latter among the spinous bones. According to a further embodiment, as illustrated in Fig. 17B, the tines can be fitted on suitable housings or slots provided on the junction element in a length included between the fixing bars 44,80.

[0085] At the same time, the device saddles are inserted onto the corresponding spinous bones, thus bringing the groove bottom in abutment against the spinous bones. Particularly, with the removal of the gripper 114, the junction element is axially preloaded, i.e. along Z-axis, in compression, so as to ensure the contact between the saddles and their respective spinous bones.

[0086] The bush notches advantageously allow to modify the relative position between the bars and the bushes, so as to be able to adapt the device to the specific physiology of the column length.

[0087] After the proper position of the fastening

elements has been set, the final locking of the device bars is then carried out by inserting and screwing the caps 68 onto the bushes 52, by means of a suitable clamping wrench inserted into the hole 69. Following this clamping, the cap 68 thrusts the connecting bar against the retainer 58, in an approaching direction to the spinous bone. The head 61 is further rotatably locked by friction against the retainer 58.

[0088] The operation of the device according to the invention will be now described herein below.

[0089] After it has been fastened to at least two vertebral bodies being adjacent to each other, the device according to the invention allows relative motions between the vertebral bodies connected to each other. These motions are of the axial, flexural and torsional type and are ensured by the yielding of the junction element.

[0090] Particularly, the device allows the axial, flexural and torsional stiffness to be uniformly and gradually distributed along the column length involved, without sudden changes which could cause excessive stresses in the so-called borderline areas, as illustrated in Figs. 19A-19C. Particularly, Figs. 19A-19C show diagrams of compression, flexural and torsional stiffness, respectively, of a device 4 according to the

present invention as compared with further possible variants of devices marked with references 150, 160. The possible device 150 only comprises stiff connecting bars being fastened to the peduncles, whereas the possible device 160 comprises stiff connecting bars among the peduncles which bars are side by side with elastic elements between the spinous bones, the elastic elements being mechanically unfastened by the connecting bars, i.e. there are no mechanical connections between the bars and the elastic elements, therefore the bars and the elastic elements are arranged in succession to each other.

[0091] The stiffness is represented in the form of histograms extending along a direction W in common. The value k0 represents the stiffness of the column length free of any stabilizing device.

[0092] In all the diagrams, the values k1,k2,k3 represent the stiffness contribution provided by peduncular bars manufactured in polymer, titanium and steel, respectively, in the sizes usually employed in the art. The values marked with k4 represent the contribution provided by the stabilizing device 160 comprising stiff connecting bars between the peduncles, side by side with elastic elements between the spinous bones, in which the elastic elements are mechanically unfastened by the

connecting bars. The values marked with k5 represent the stiffness contribution provided by the stabilizing device according to the invention. It should be noted that the stabilizing device according to the invention, compared to the other devices, always ensures the less discontinuity among the stiffness of the column length and hence a gradual stress distribution both between the vertebrae directly connected to each other, and between the vertebrae adjacent to each other in the borderline zones.

[0093] The fastening elements directly connect the coupling portions to the fixing bars. Thereby, the stresses on the column length are uniformly and gradually distributed both on the spinous bones and the peduncles.

[0094] The compressed preload of the junction element, following the insertion of the same between the vertebral bodies, ensures a continuous contact between the fastening elements and the spinous bones. Thereby, the loads are always also distributed on the spinous bones, besides on the peduncles.

[0095] The stiffness of the column length involved with the device, as compared with the physiology of the sound column length, is also gradually and uniformly modified without sudden changes occurring both in the axial,

flexural and torsional stiffness. By extending the fixing bars, the loads of the column length, as well as its respective stiffness, can be distributed on an increasing number of vertebrae, so as to respect the column length physiology as much as possible. Thereby, sudden changes in stiffness at the borderline zones or areas, i.e. the column zones adjacent to the device, do not occur.

[0096] As may be appreciated from what has been described, the described device allows one to overcome the drawbacks occurred in the prior art.

[0097] Particularly, the device allows a uniform load distribution between the peduncles and the spinous bones of the vertebral bodies.

[0098] Thereby, the borderline zones are loaded gradually, without the presence of sudden load changes.

[0099] In fact, each stiffness of the vertebral bodies gradually change from one another, without sudden discontinuities.

[00100] Furthermore, the spinous bones are suitably loaded, i.e. they are not overloaded because they are not intended to suffer all the stresses transmitted between two contiguous vertebrae; the risk of dangerous breaks of the latter is thus avoided. In other words, the load burdening the vertebral bodies is not totally

discharged on the spinous bones, but it is suitably distributed between the spinous bones and the peduncles.

[00101] The loads burdening the spinal length related to the device according to the invention, are advantageously distributed both on the spinous bones and on the peduncles of the vertebral bodies; thereby, sudden, dangerous changes in the stress distribution on the vertebrae adjacent to said spinal length, the so-called borderline zones, do not occur.

[00102] The device may be also easily implanted on a spinal length thanks to the possibility of adjustment offered by the lock bushes. This adjustment is both axial, i.e. either a sliding or a relative translation between the connecting bars and the bush notches, and angular, i.e. an orientation of the bush notches.

[00103] The presence of the junction element provided with helical-course grooves ensures both a flexural and torsional proper stiffness so as to ensure but also support the normal flexural and torsional motions of the column.

[00104] The device according to the invention is capable of maintaining the kinematics of the column segment to which it is connected and at the same time it is capable of providing an elastic support and acting as a damper being interposed between the spinous bones of

the vertebral bodies of the same segment.

[00105] The device ensures the main physiological functions of the intervertebral disks, such as the correct kinematics for example of the rachis and the ability of transferring the loads and dampening the dynamic stresses.

[00106] The joint allows movements and bending and also acts as a shock absorber.

[00107] The interaction between the peduncular bars, fastened to the peduncles of the vertebral bodies, and the joint associated to the spinous bones ensures a proper and gradual load distribution not only on the column length related to the device but also on the borderline zones, i.e. on the adjacent vertebrae.

[00108] With this interaction the spinous bones are not overloaded and at the same time a part of the loads is absorbed by the adjacent and thus sound vertebral bodies.

[00109] The device does not cause arthrodesis, thus always ensuring the correct kinematics between the vertebral bodies.

[00110] Those skilled in the art, aiming at satisfying contingent and specific needs, will be able to carry out several modifications and variants to the intervertebral devices described above, all of them being contemplated

within the scope of the invention such as defined by the following claims.

CLAIMS

1. An intervertebral stabilizing device (4), adapted to be interposed between at least a first (8) and a second (12) vertebrae being adjacent to each other,
comprising a first fastening element (32), adapted to be associated to said first vertebra (8),
and a second fastening element (34), adapted to be associated to said second vertebra (12),
said first and second fastening elements (32,34) each comprising a coupling portion (38,72) adapted to be coupled with a spinous bone (20,28) of the first and second vertebrae (8,12), respectively,
said first and second fastening elements (32,34) being operatively connected to each other by means of a junction element (84) adapted to allow relative motions between said fastening elements (32,34)
characterized in that
at least one of said fastening element (32,34) comprises fixing bars (44,80) adapted to be fastened to peduncles (18,26) of at least one of said first and second vertebrae (8,12), so as to discharge the forces exchanged between the first and second vertebrae (8,12) both on the spinous bones (20,28) of said vertebrae (8,12) and the peduncles (18,26) of at least one of said

vertebrae (8,12).

2. The intervertebral stabilizing device (4) according to claim 1, wherein said first and second fastening elements (32,34) comprise first and second fixing bars (44,80), respectively, adapted to be fastened to their respective peduncles (18,26) of the first and second vertebrae (8,12).

3. The intervertebral stabilizing device (4) according to claim 1 or 2, wherein the first coupling portion (38) has either a saddle- or a 'U'-shaped configuration, comprising two branches (39) so as to be fitted on the first spinous bone (20) according to a shape coupling.

4. The intervertebral stabilizing device (4) according to claim 3, wherein to said first coupling portion (38) is associated the first pair of fixing bars (44) so that the stresses transmitted to the first fastening element (32) are distributed both on the first spinous bone (20) and the first pair of peduncles (18).

5. The intervertebral stabilizing device (4) according to any preceding claim, wherein said first fixing bars (44) are oriented so that, on a plane perpendicular to a symmetry plane (S') of the first vertebra (8), they are angled according to a first incidence angle (α') relative to a vertical axis (Z) of the first vertebra (8) so as to intercept the first pair of peduncles (18).

6. The intervertebral stabilizing device (4) according to claim 5, wherein said first incidence angle (α') ranges between 0 and 20 degrees.

7. The intervertebral stabilizing device (4) according to claim 6, wherein said first incidence angle (α') is equal to 12 degrees.

8. The intervertebral stabilizing device (4) according to any preceding claim, wherein the second coupling portion (72) has either a saddle- or a 'U'-shaped configuration, comprising two second branches (74) so as to be fitted on the second spinous bone (28) according to a shape coupling.

9. The intervertebral stabilizing device (4) according to claim 8, wherein to said second coupling portion (72) is associated the second pair of fixing bars (80) so that the stresses transmitted to the second fastening element (34) are distributed both on the second spinous bone (28) and the second pair of peduncles (26).

10. The intervertebral stabilizing device (4) according to claim 8 or 9, wherein said second fixing bars (80) are oriented so that, relative to a plane which is perpendicular to a symmetry plane (S") of the second vertebra (8), are angled of a second incidence angle (α") so as to intercept the second pair of peduncles (18).

11. The intervertebral stabilizing device (4) according to claim 10, wherein said second incidence angle (α") ranges between 0 and 20 degrees.

12. The intervertebral stabilizing device (4) according to claim 11, wherein said second incidence angle (α") is equal to 12 degrees.

13. The intervertebral stabilizing device (4) according to any preceding claim, wherein at least one of said first and second fastening elements (32,34) comprises fastening screws (50) adapted to firmly fasten the fastening elements (32,34) to the peduncles (18,26) of the vertebrae (8,12).

14. The intervertebral stabilizing device (4) according to claim 13, wherein the fastening screws (50) comprise a bush (52) comprising a notch (64), extending along a diameter of the bush (52) and having a thickness which is not lower than the thickness of the fixing bars (44,80) so as to house a portion of said fixing bars (44,80) in order to allow the screws (50) to be coupled with the fixing bars (44,80).

15. The intervertebral stabilizing device (4) according to any preceding claim, wherein the anchoring between the spinous bones (20,28) and the coupling portions (38,72) is carried out by means of little strings passing around the spinous bones (20,28) and through

suitable coupling holes provided on said coupling portions (38,72).

16. The intervertebral stabilizing device (4) according to any preceding claim, wherein the coupling portions (38,72) are fastened to the spinous bones (20,28) by means of dowels (79) at least partially passing through the coupling portions (38,72) and the spinous bones (20,28).

17. The intervertebral stabilizing device (4) according to any preceding claim, wherein said junction element (84) is a flexible element adapted to allow rotary, translatory and flexural motions among the fastening elements (32,34).

18. The intervertebral stabilizing device (4) according to any preceding claim, wherein the junction element (84) comprises a cylindrical body (86) provided with a plurality of notches (88), being arranged on the circumference of the latter, said notches (88) having a radial depth which is lower than the radius of the cylindrical body (86), so as to provide a helical spring.

19. The intervertebral stabilizing device (4) according to claim 18, wherein the cylindrical body (86) is provided with a single notch being helically arranged so as to provide a single continuous spiral.

20. The intervertebral stabilizing device (4) according to claim 18 or 19, wherein the cylindrical body (86) is provided with a central cylindrical hole (91).

21. The intervertebral stabilizing device (4) according to claim 20, wherein the central cylindrical hole (91) is provided with a diameter equal to about 1/3 of the outer diameter of the same cylindrical body.

22. The intervertebral stabilizing device (4) according to any preceding claim, wherein said junction element (84) is a joint of the ball type (92), adapted to allow relative rotary motions among the same elements.

23. The intervertebral stabilizing device (4) according to claim 22, wherein the joint of the ball type (92) comprises a spring elastic element therein, so as to dampen the relative motion between the fastening elements (32,34).

24. The intervertebral stabilizing device (4) according to any preceding claim, wherein the connecting bars (44,80) comprise flexible elements (97) so as to ensure further flexibility to the connecting bars, as well as a better adjustment of the connecting bars to the column length morphology.

25. The intervertebral stabilizing device (4) according to claim 24, wherein said flexible elements (97) comprise a cylindrical body provided with a helical

continuous groove and a central hole, being coaxial with said cylindrical body.

26. A medical kit for the intervertebral stabilization comprising an intervertebral device (4) according to any preceding claim and a template tool (98) for assembling said device (4), said template tool (98) comprising a first and a second measuring elements (100,102) each adapted to be interfaced with the spinous bones (20,28) of the two adjacent vertebral bodies (8,12), each of said measuring elements (100,102) comprising a saddle portion (104), adapted to be fitted on its respective spinous bone, and a pair of slotted links (106), symmetrically arranged relative to said saddle portion (104), so as to intercept the peduncles of their respective vertebral bodies.

27. The medical kit according to claim 26, wherein each slotted link (106) is provided with a groove (108) adapted to allow either a point of a drift (110) or a marking tool for marking the peduncles of the vertebrae (8,12) to pass through.

28. The medical kit according to claim 26 or 27, wherein the measuring elements (100,102) can be axially adjusted to each other, along a mutual extension axis Y by means of a screwdriver (112), a connecting portion between the two measuring elements (100,102) being

provided with a graduated scale, in order to provide a direct measuring of the size of the device (4) which is more easily adapted to the column length.

29. The medical kit according to any claim 26 to 28, comprising a gripper having a pair of grip elements (116,118) slidingly associated on each other at a first end (120), and each is provided with a pair of tines (126), at a second end (124) being opposite to said first end (120), adapted to grasp the device at the junction element (84).

30. The medical kit according to any claim 26 to 29, wherein the gripper (114) is provided with a gauged screw (130) adapted to adjust the axial distance between the two grip elements (116,118) which can relatively slide on each other.

31. An intervertebral stabilizing method, comprising the steps of:

- evaluating the morphology of the column length to be stabilized, by measuring the distance between two spinous bones (20,28) of two vertebrae (8,12) adjacent to each other,
- marking the zone of the peduncles (18,26) on which the device (4) requires to be fastened,
- fastening the fastening screws (50) on the peduncles (18,26) so as to orientate the notches (64) of the

bushes (52) in a parallel manner to the final arrangement which the connecting bars (44,80) of the fastening elements (32,34) will have to take,

- grasping and fitting the device (4) between the vertebral bodies, by inserting the bars of the first and second fastening elements (32,34) into their respective notches (64) of the bushes and by inserting the coupling portions (38,72) of the device onto the corresponding spinous bones (20,28).

32. The intervertebral stabilizing method according to claim 31, comprising the step of final locking of the device bars by inserting and screwing the caps (68) onto the bushes (52).

33. The intervertebral stabilizing method according to claim 31 or 32, wherein said evaluating step of the morphology of the column length to be stabilized, is carried out by fitting a template tool (98) provided with two measuring elements between the spinous bones (20,28) of the vertebrae (8,12) and by adjusting the axial position between the two measuring elements (100,102).

34. The intervertebral stabilizing method according to claim 33, wherein the marking step of the peduncles (18,26) is carried out with the aid either of a drift (110) or a marker, by inserting the latter through

grooves (108) provided on slots (106) of the template tool.

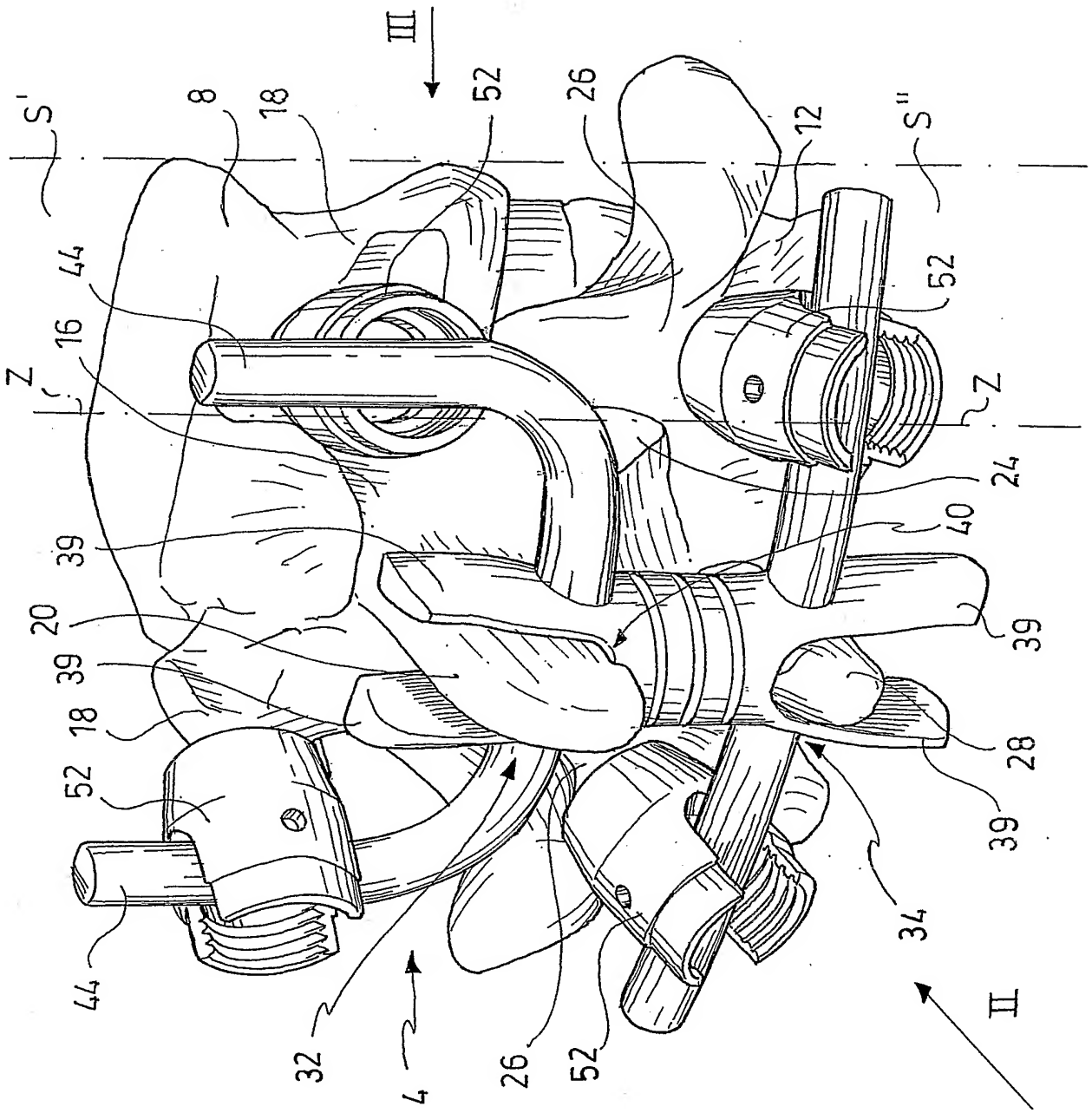

III
S'
S''
8
18
52
26
12
44
16
Z
Z
52
24
40
39
20
39
39
18
52
28
39
44
32
4
26
52
34
II

FIG. 1

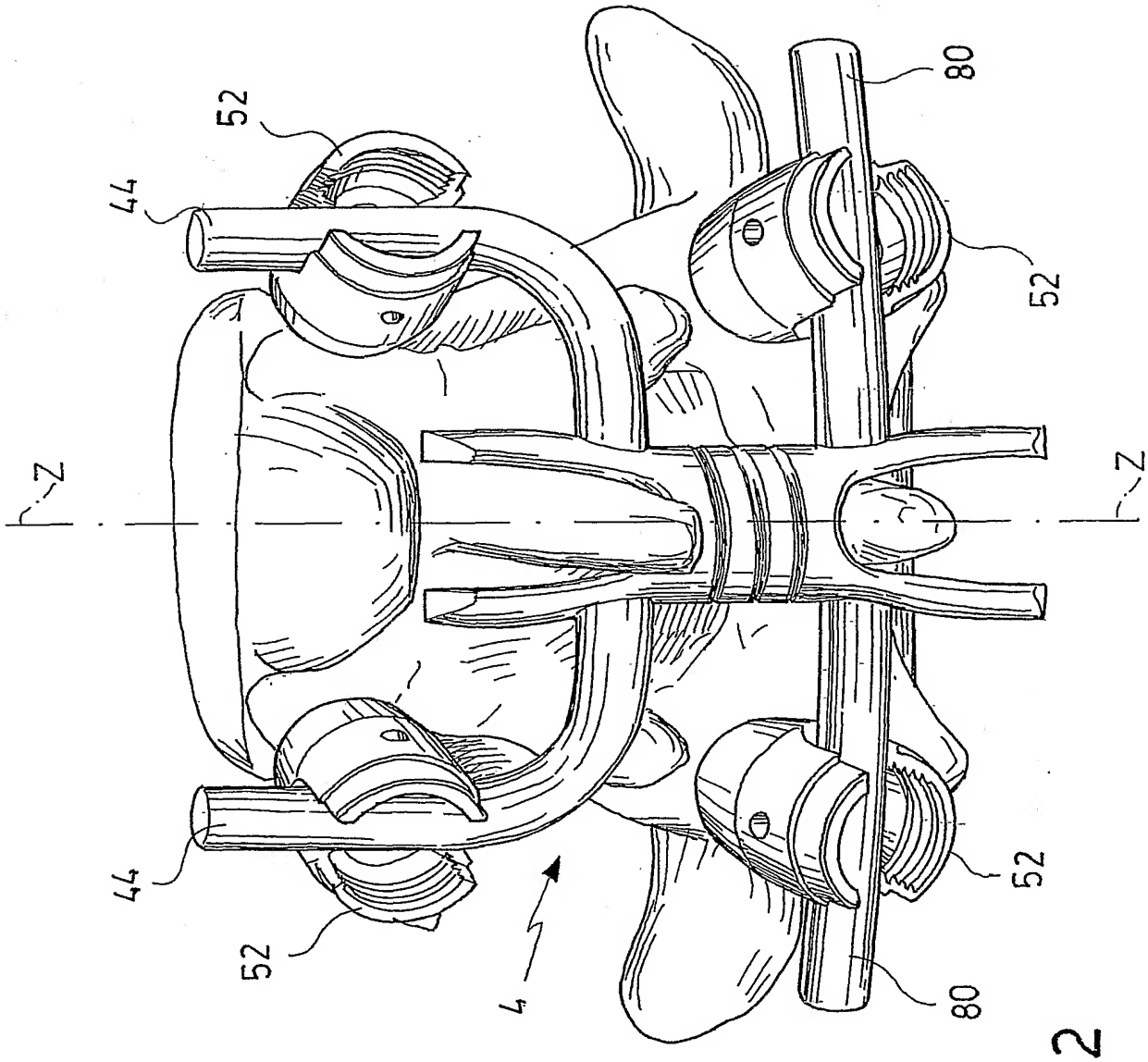


FIG.2

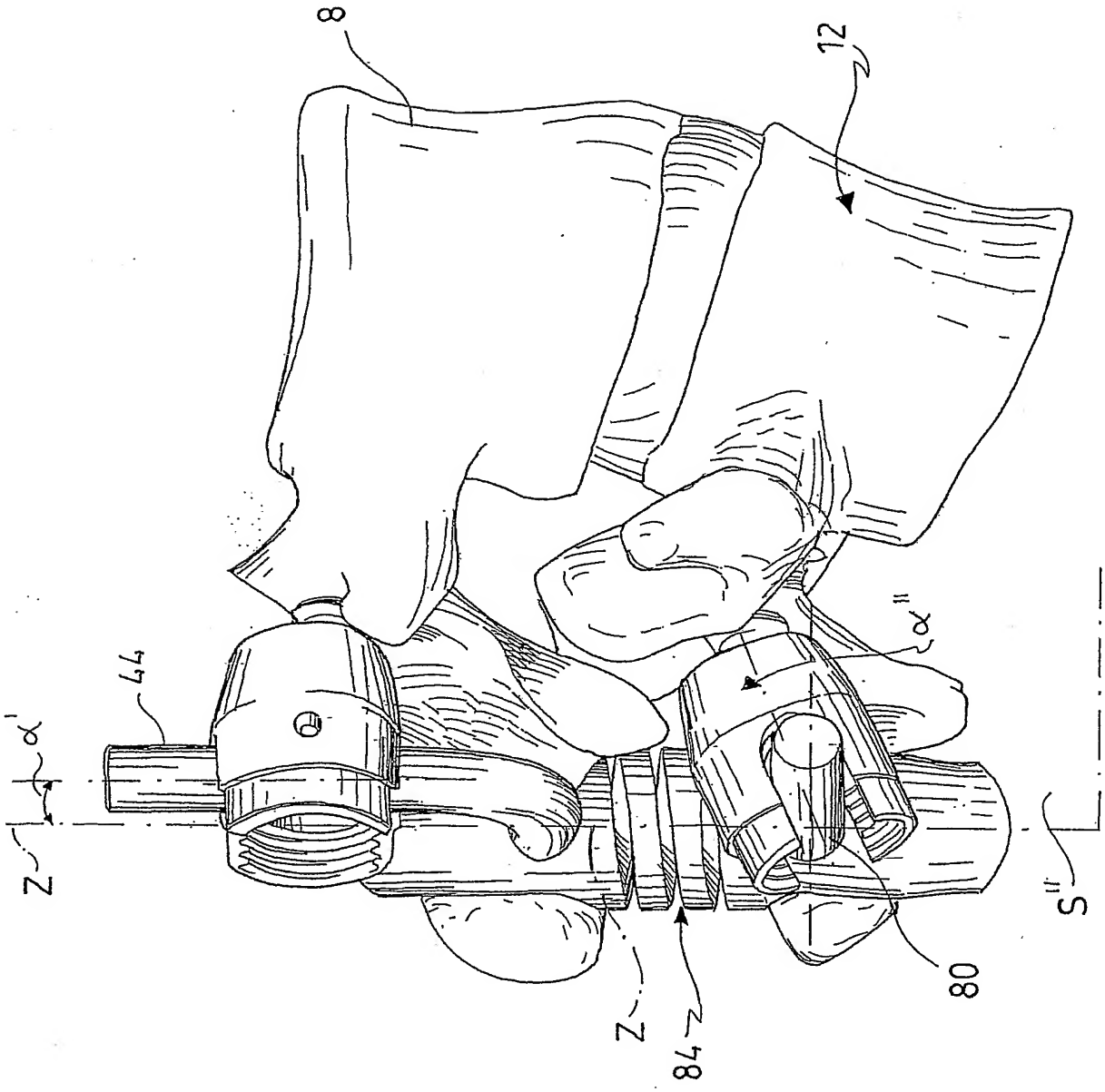


FIG.3

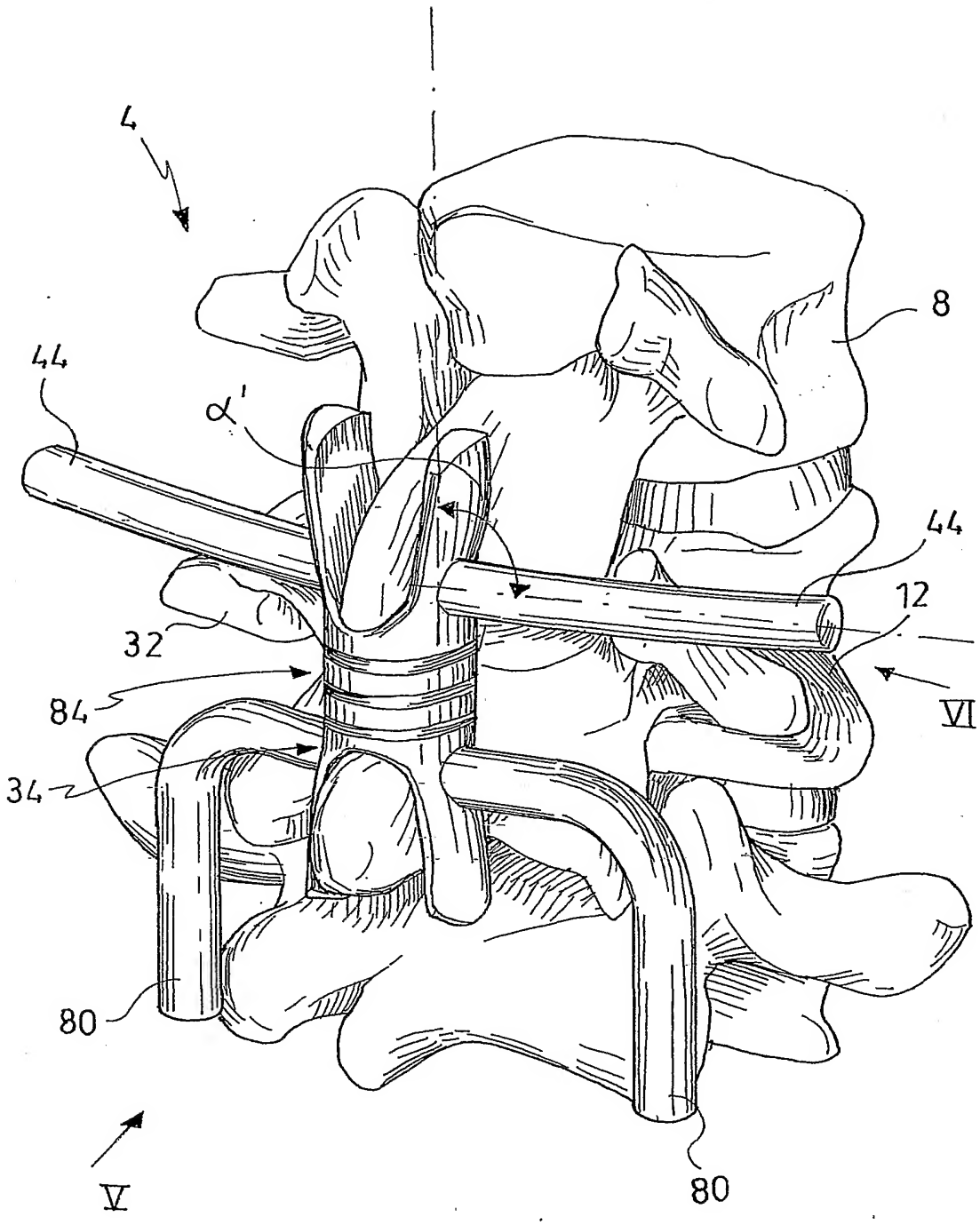


FIG. 4

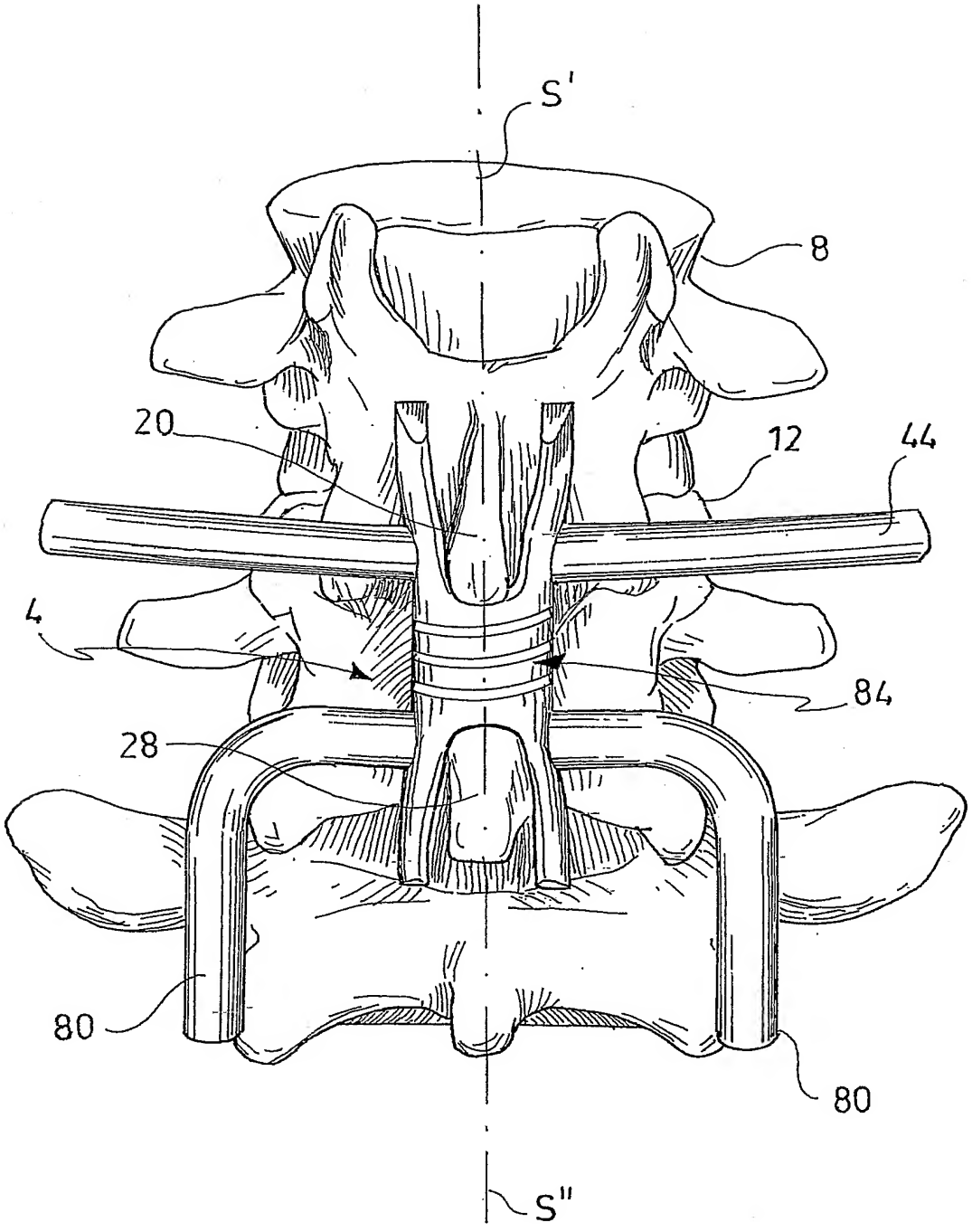


FIG.5

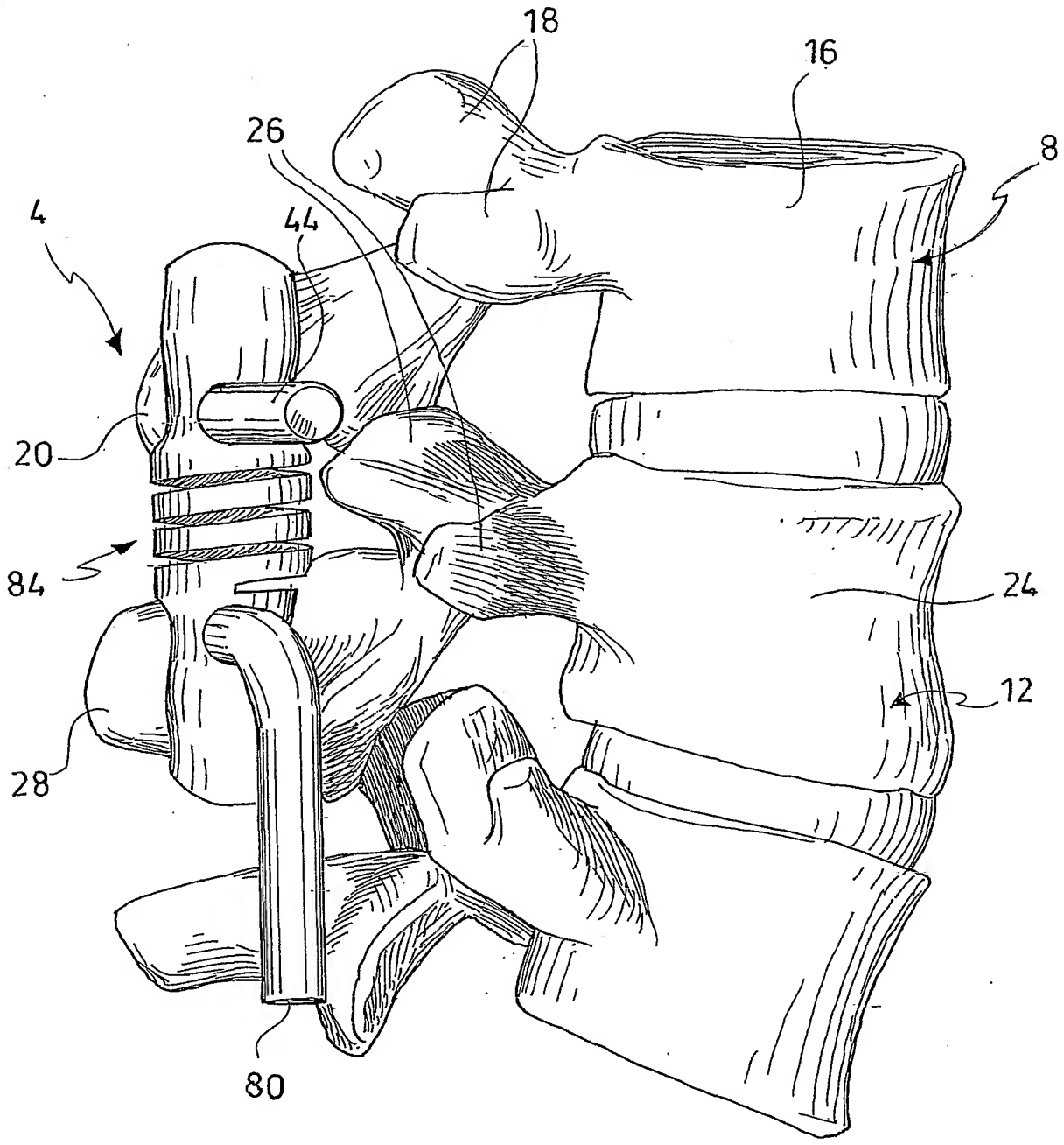


FIG. 6

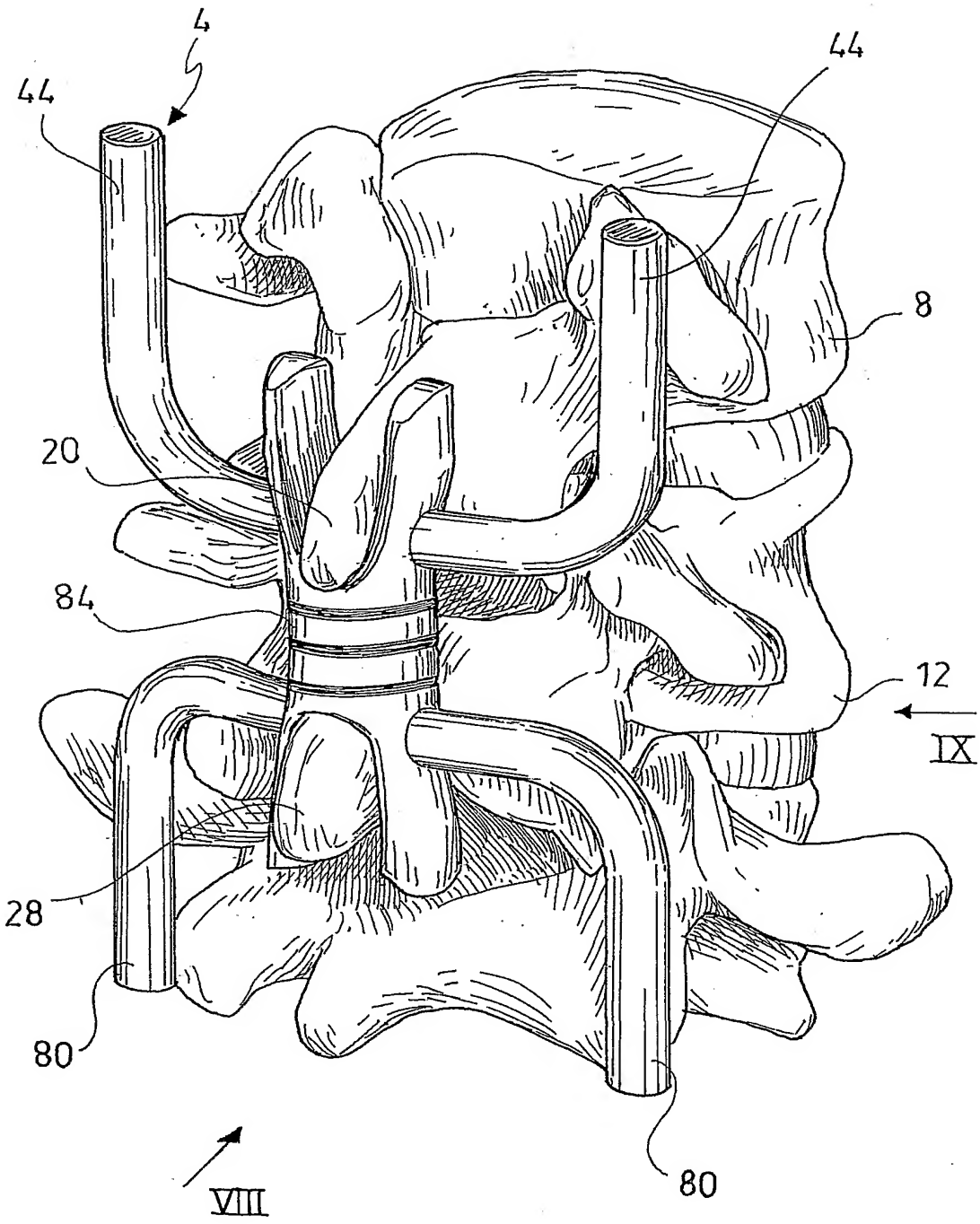


FIG. 7

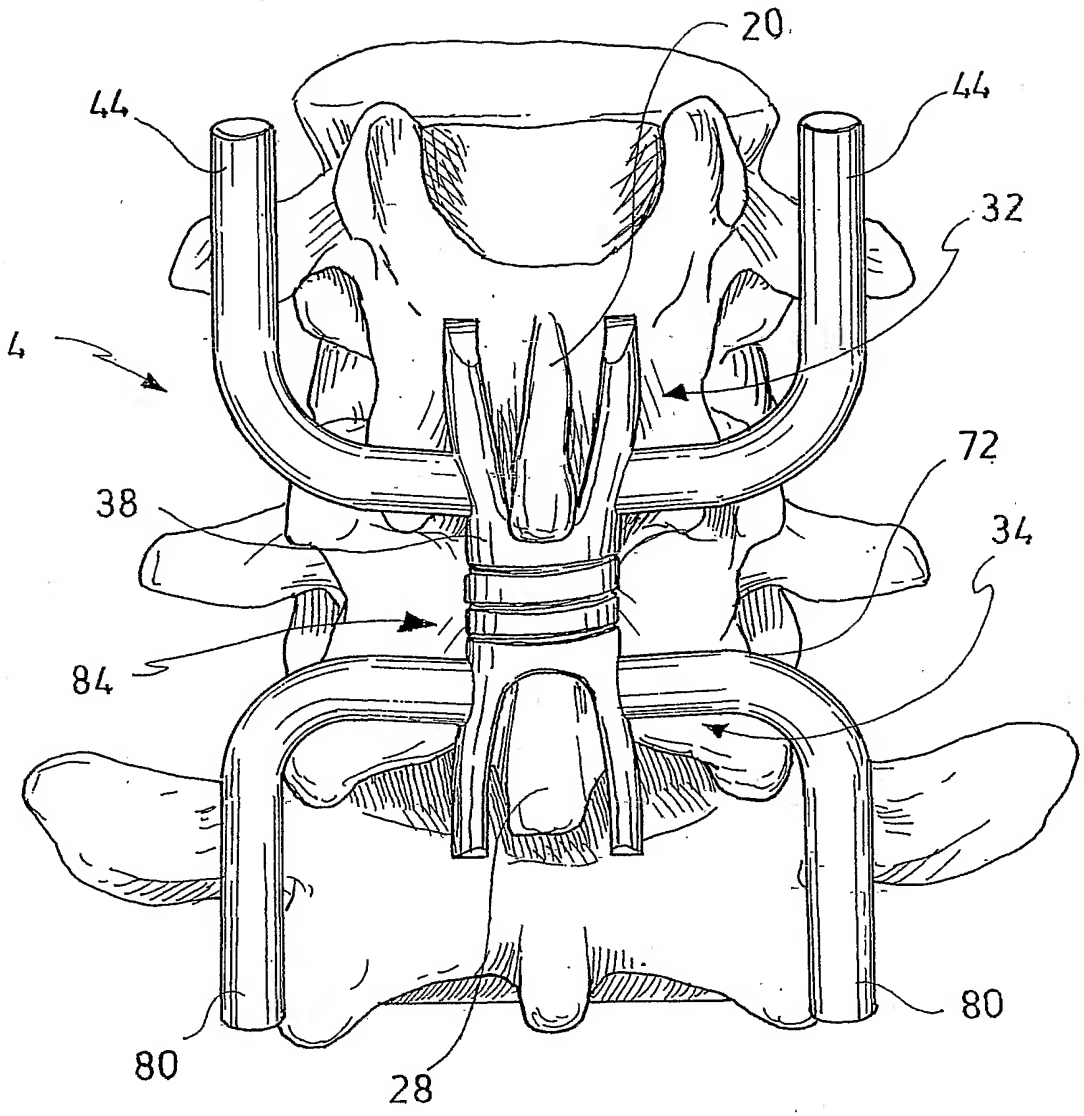


FIG.8

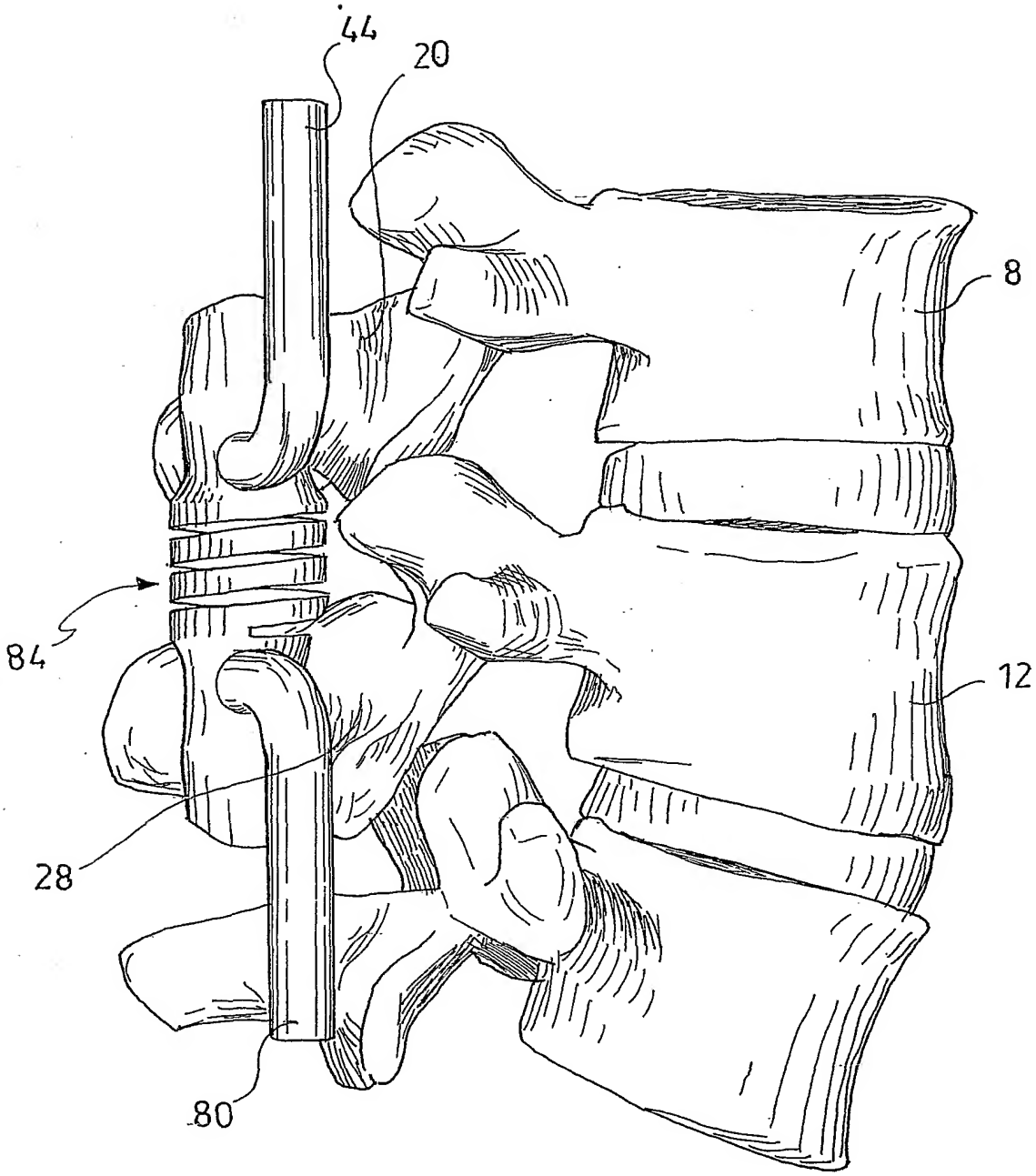


FIG. 9

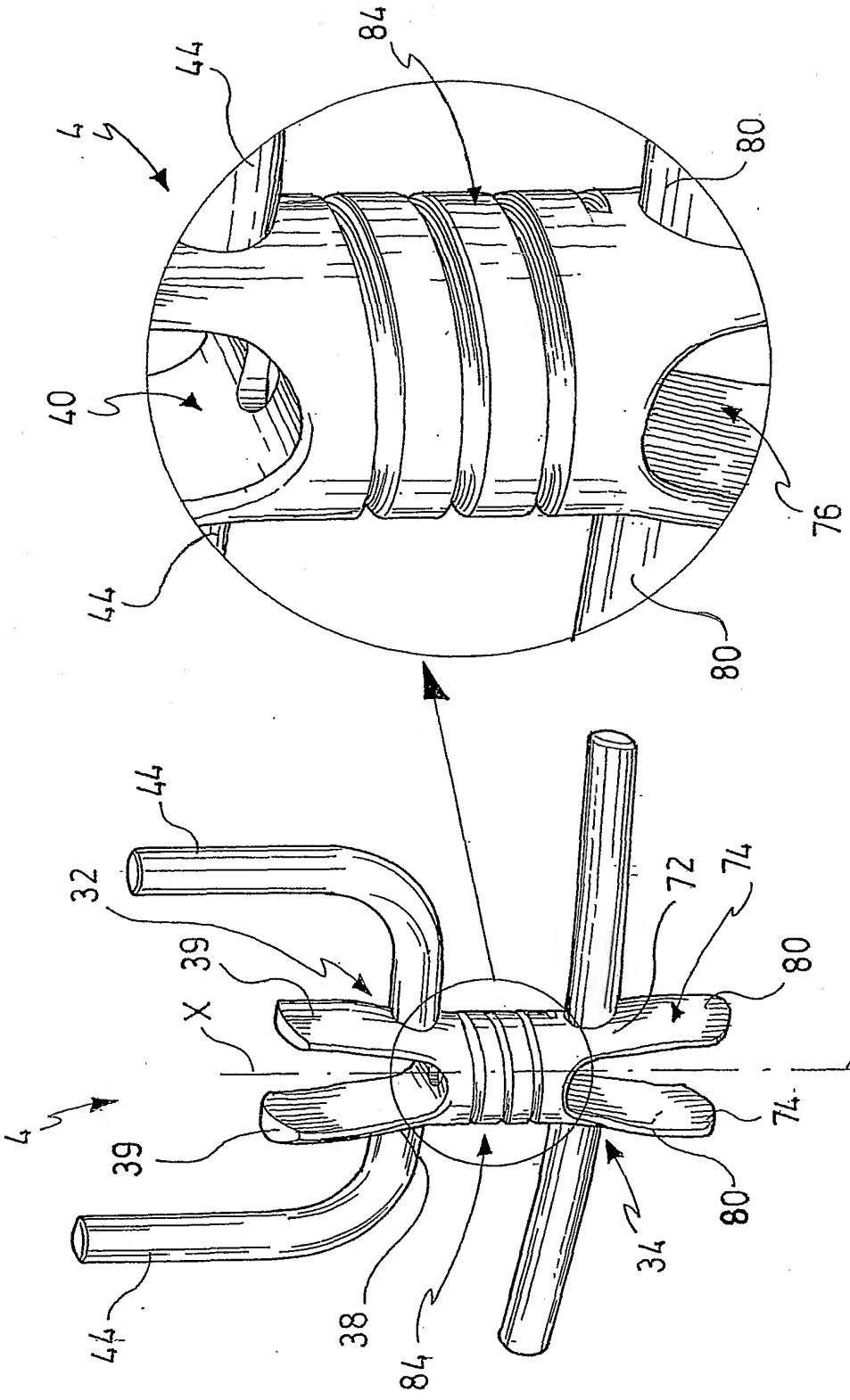


FIG.10A

FIG.10

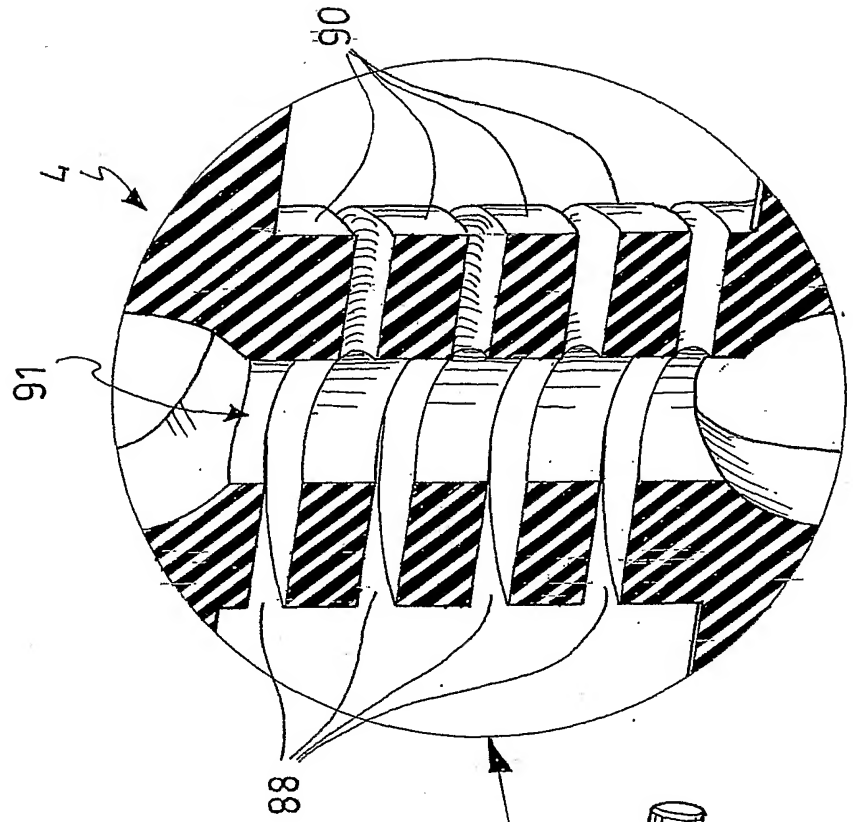


FIG.11A

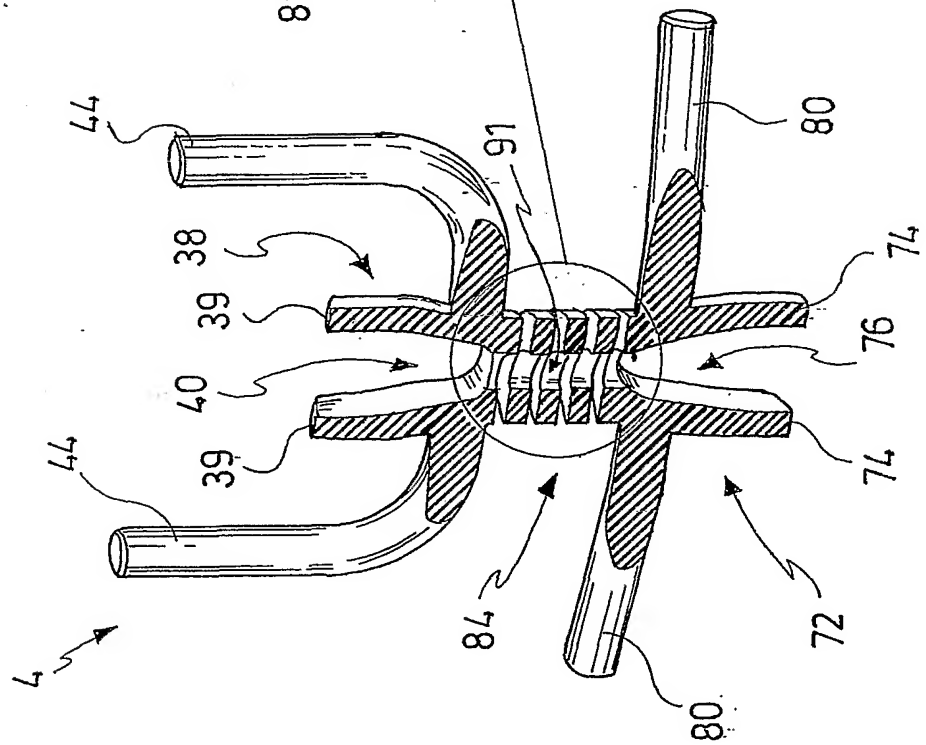


FIG.11

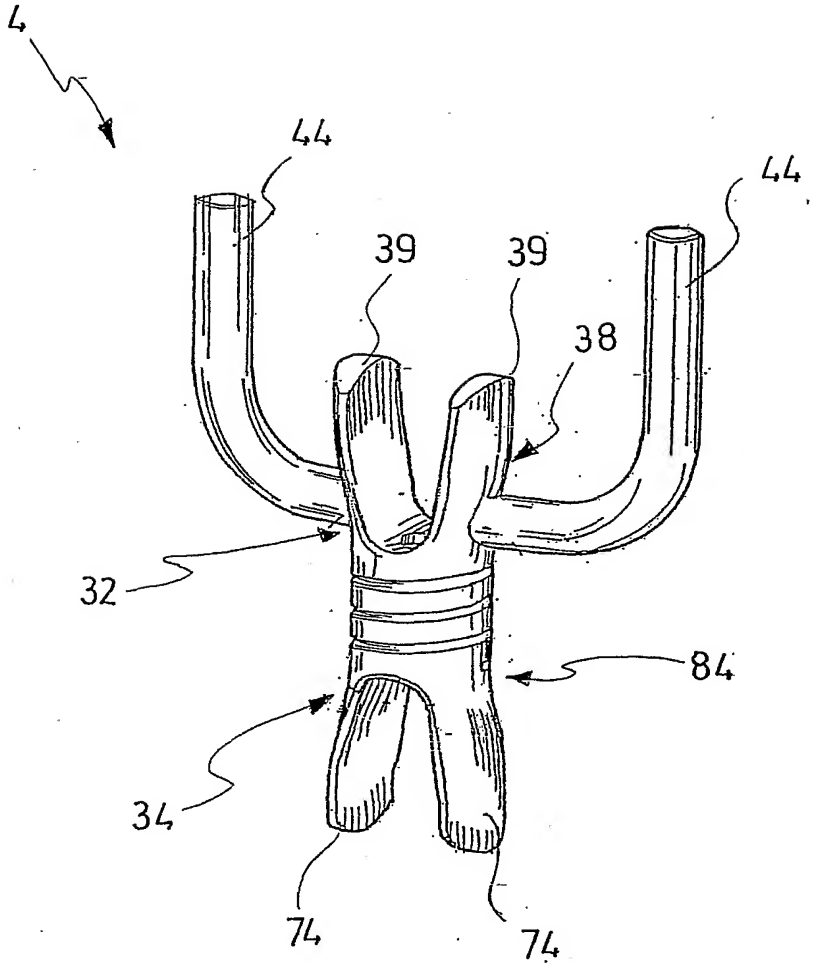


FIG.12A

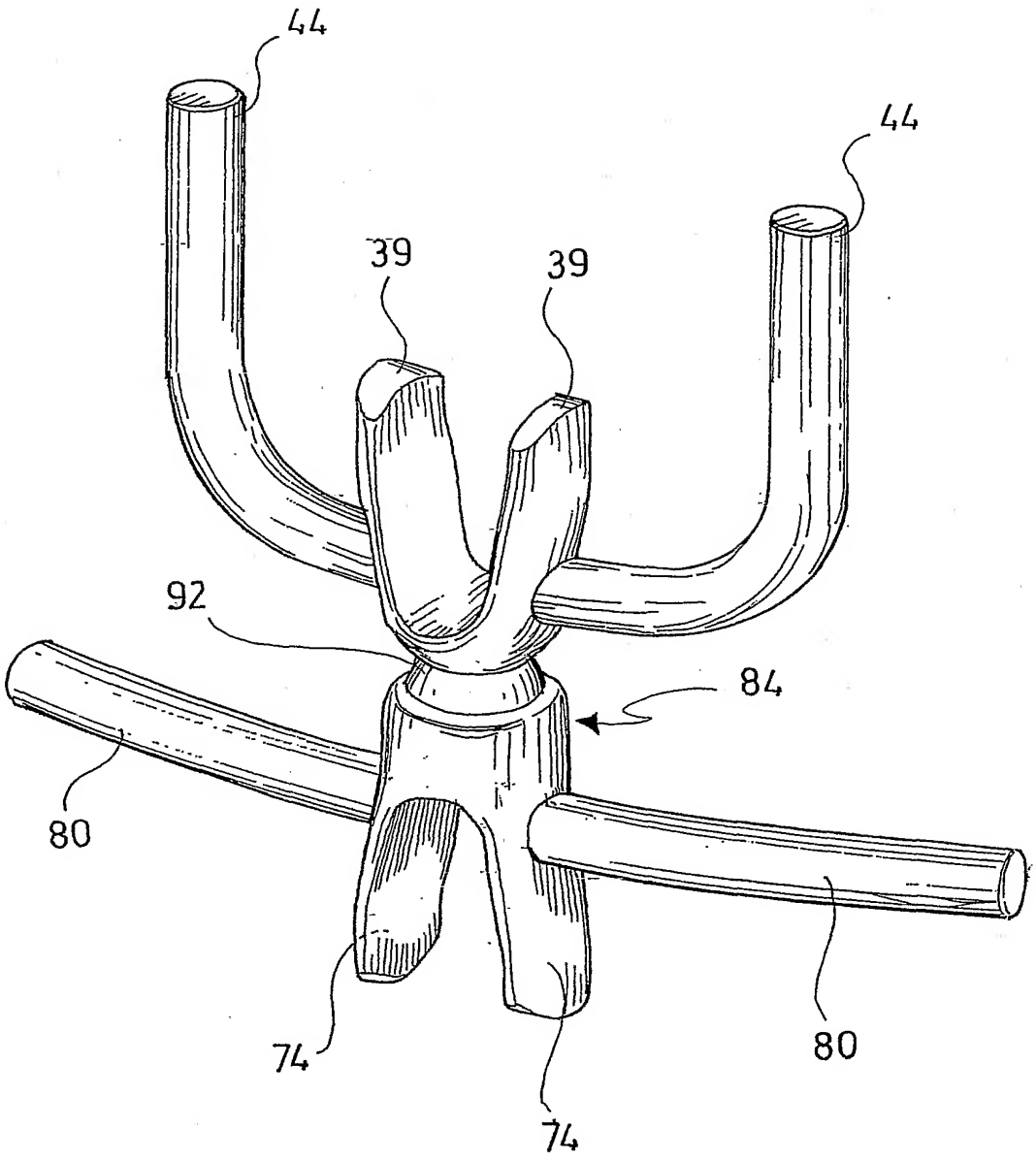


FIG. 12B

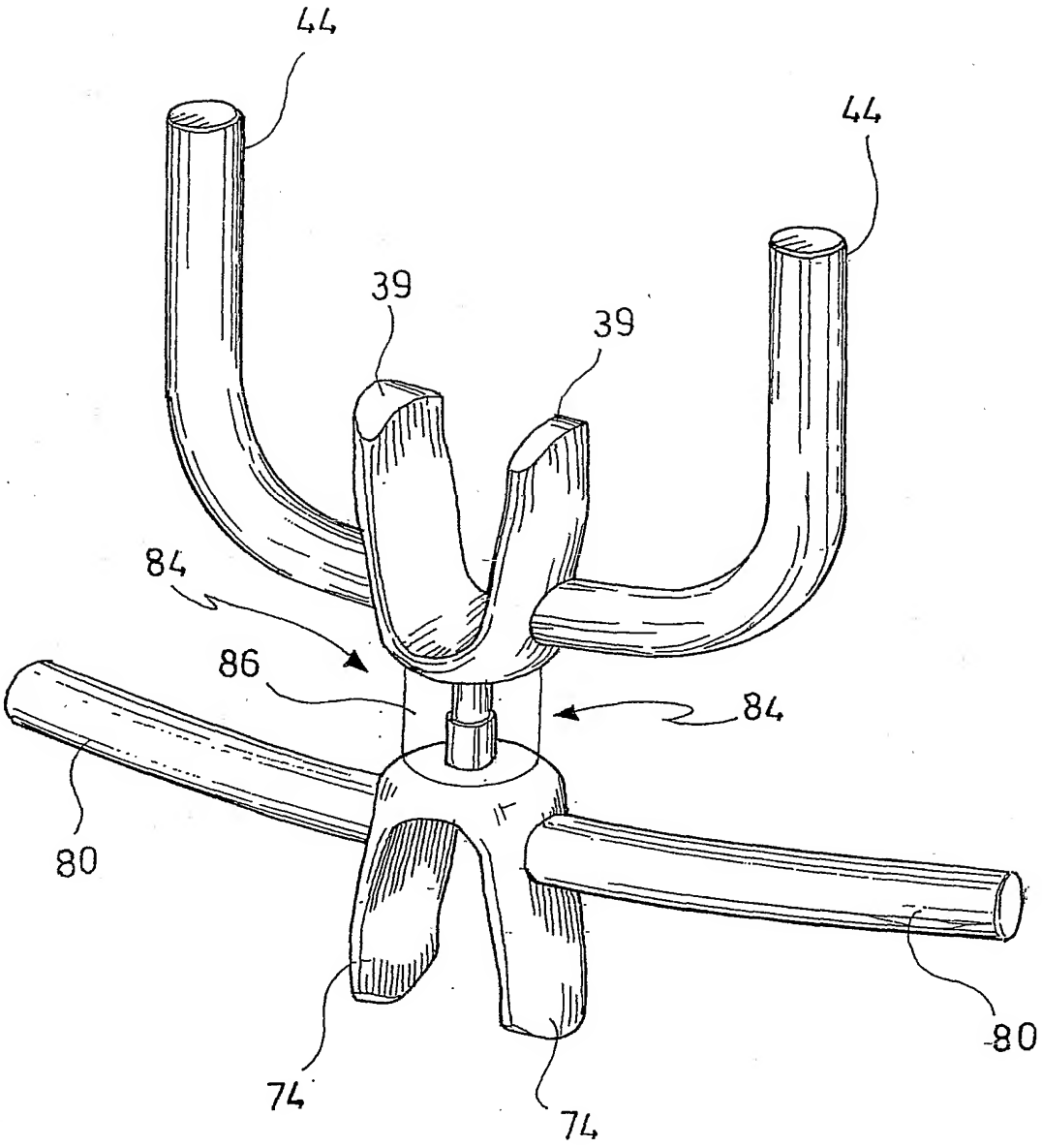


FIG. 13A

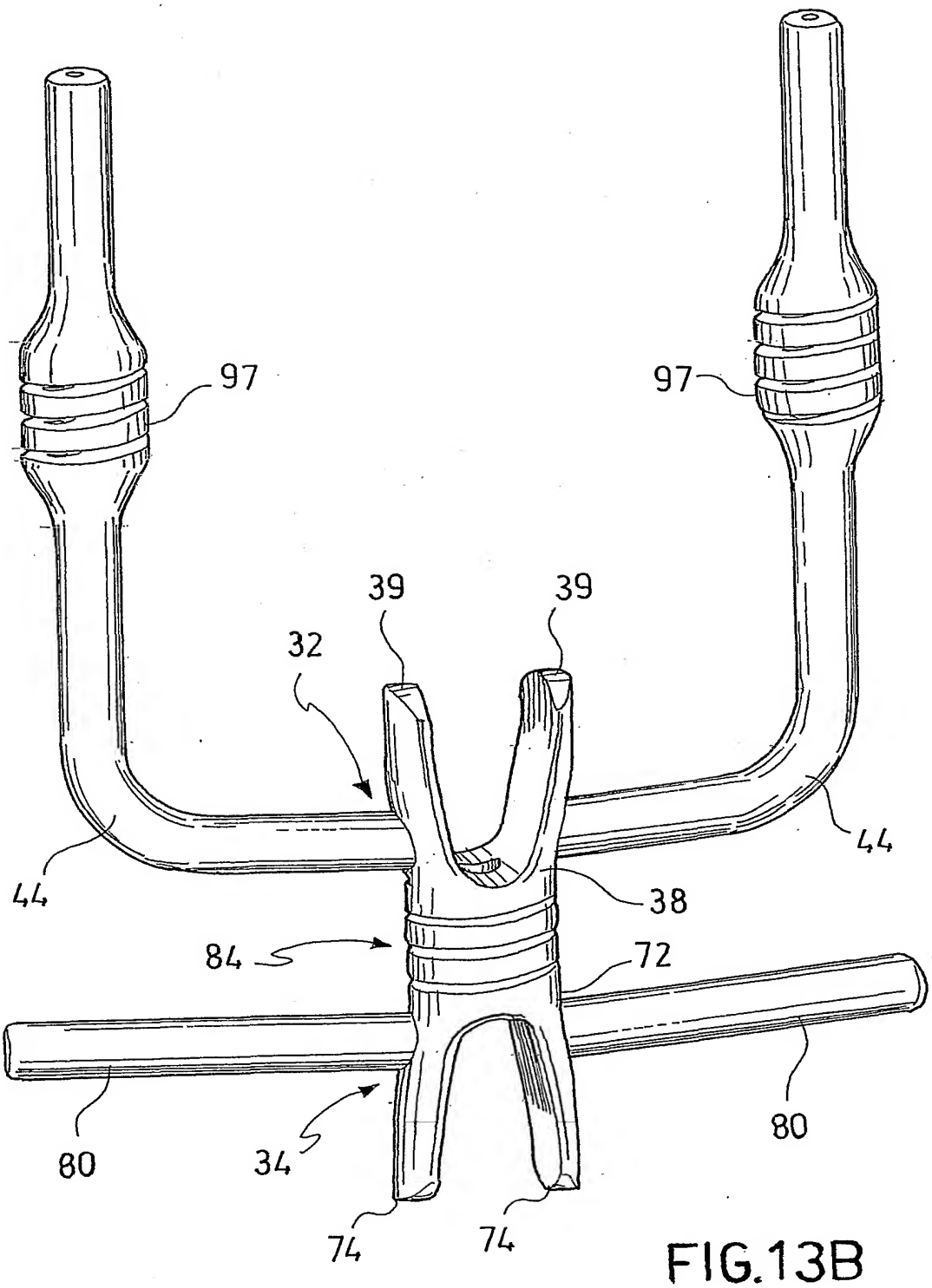
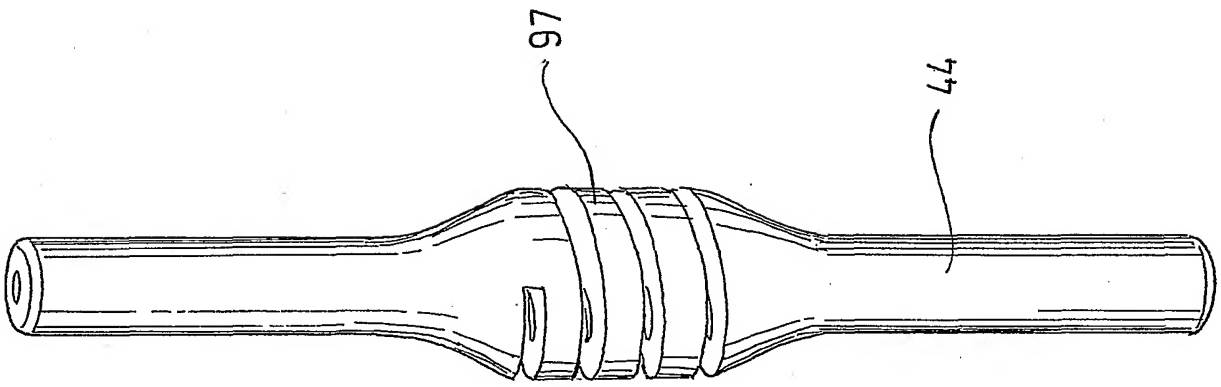


FIG.13B

FIG.13C



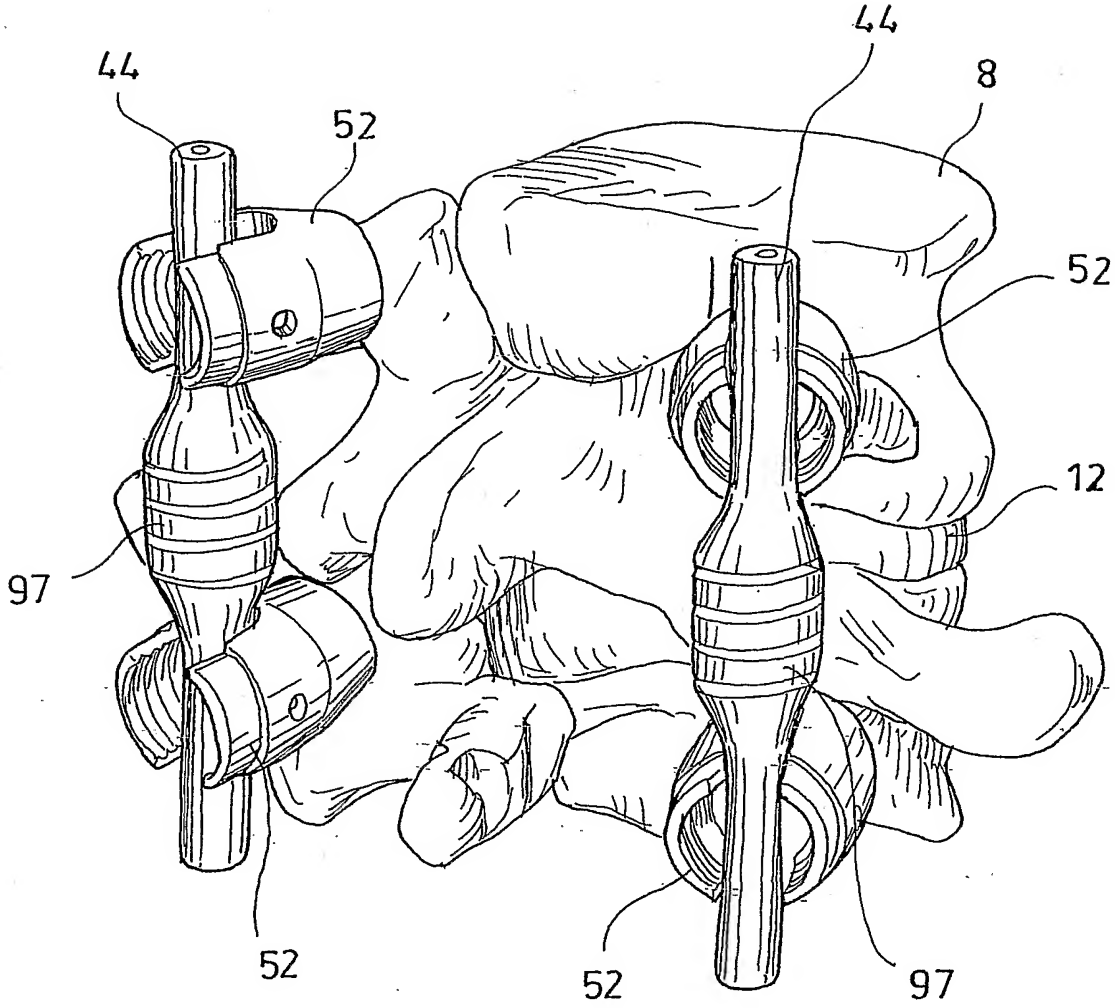


FIG.13D

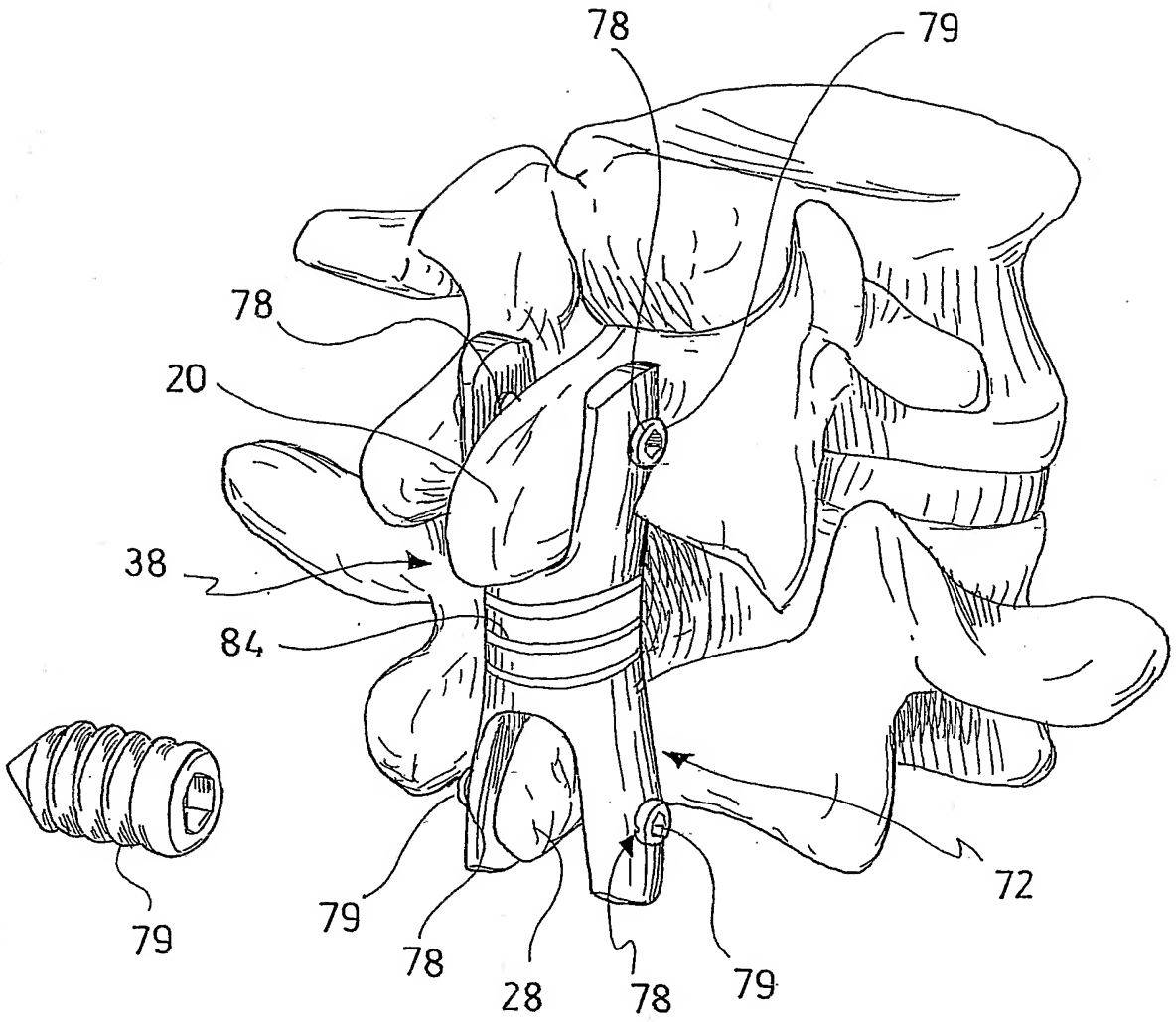


FIG.13E

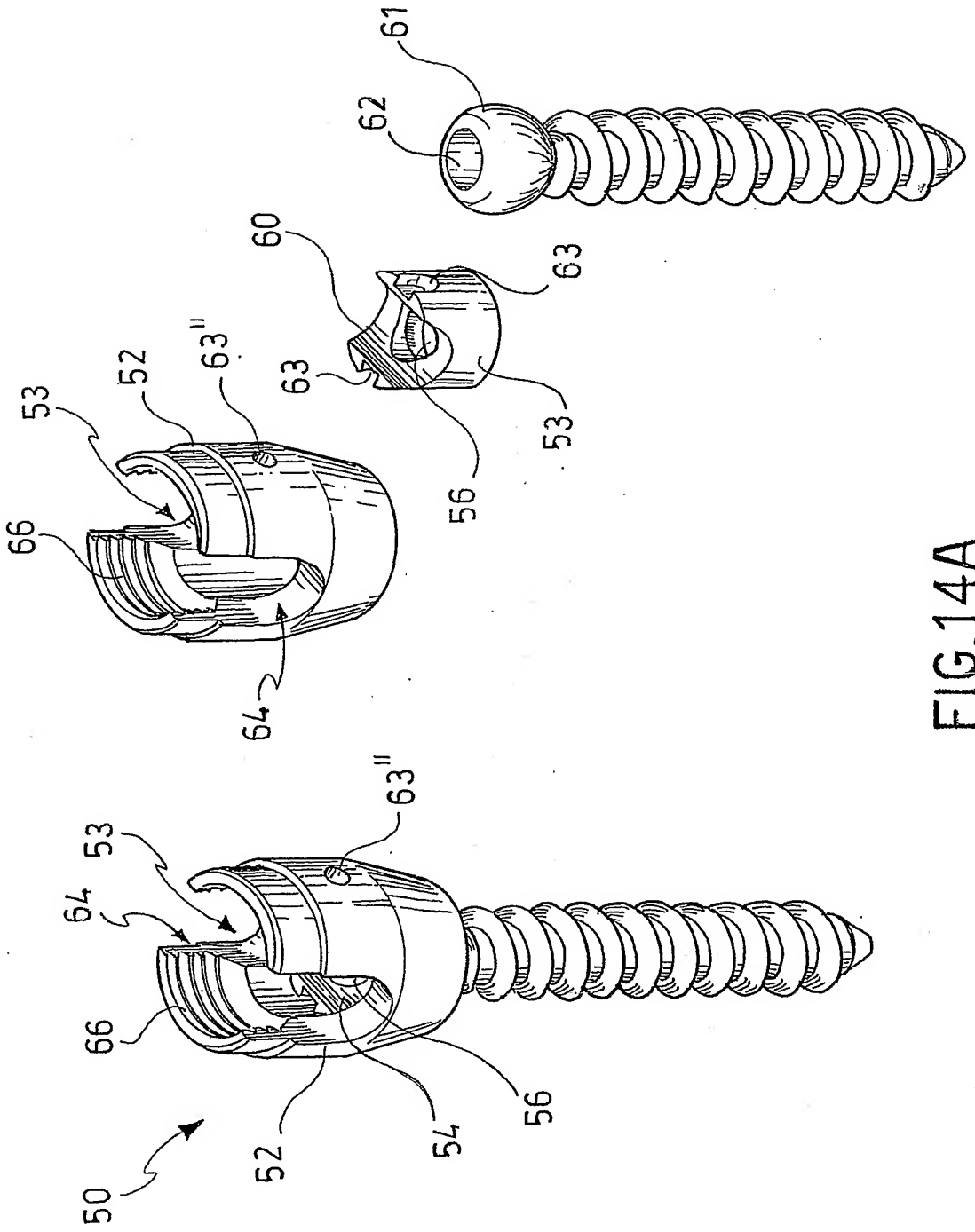


FIG.14A

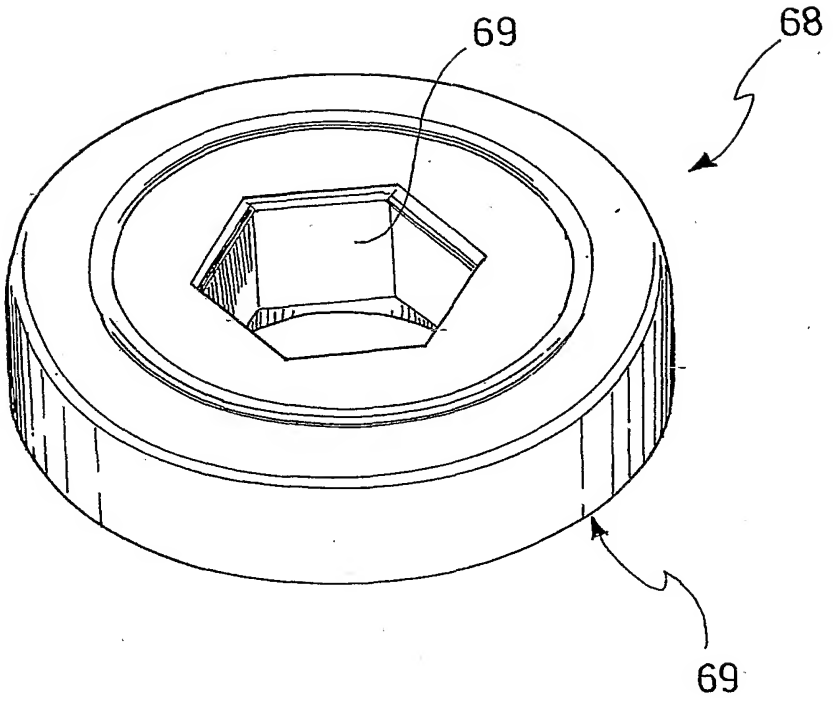


FIG.14B

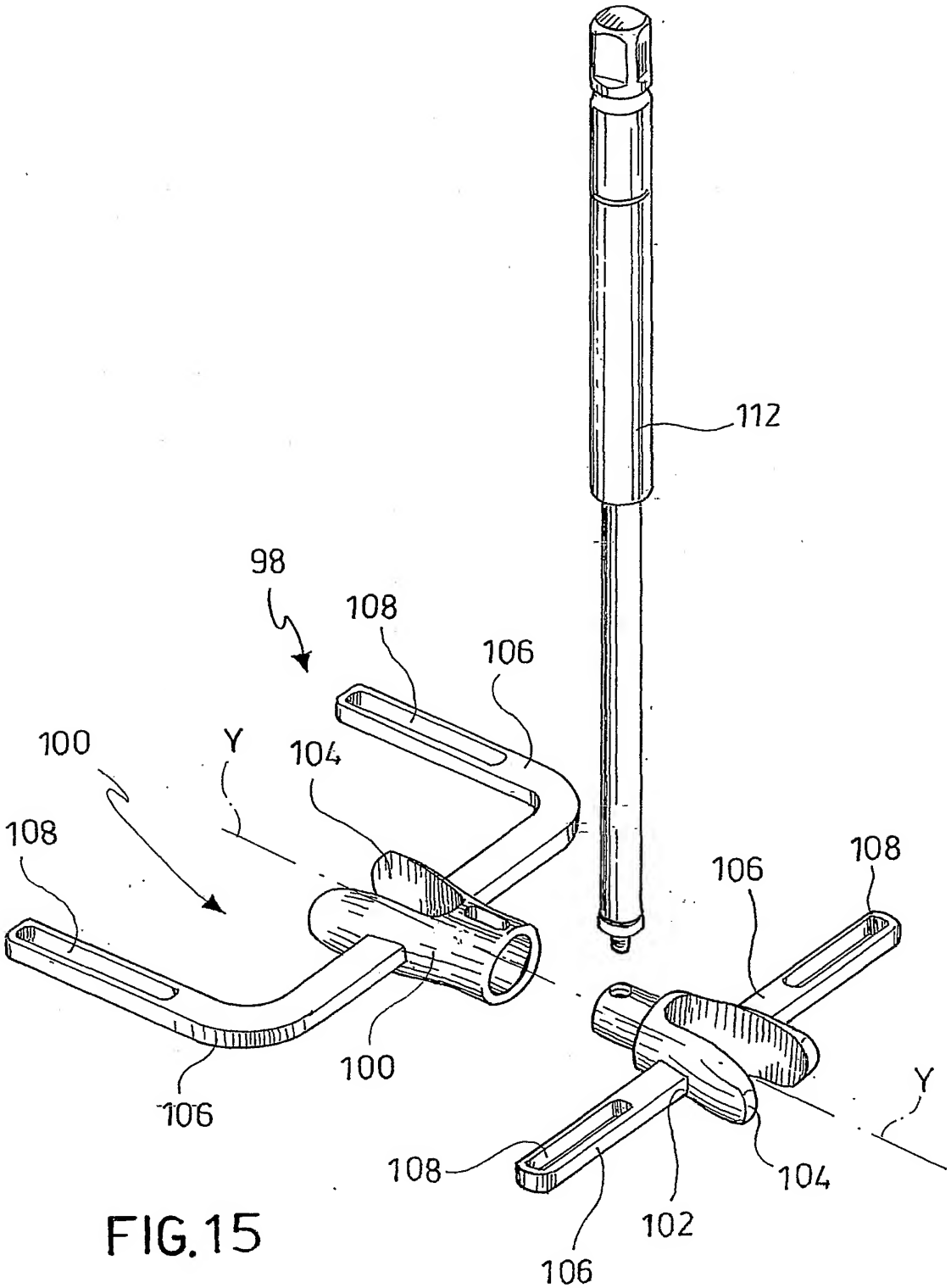


FIG.15

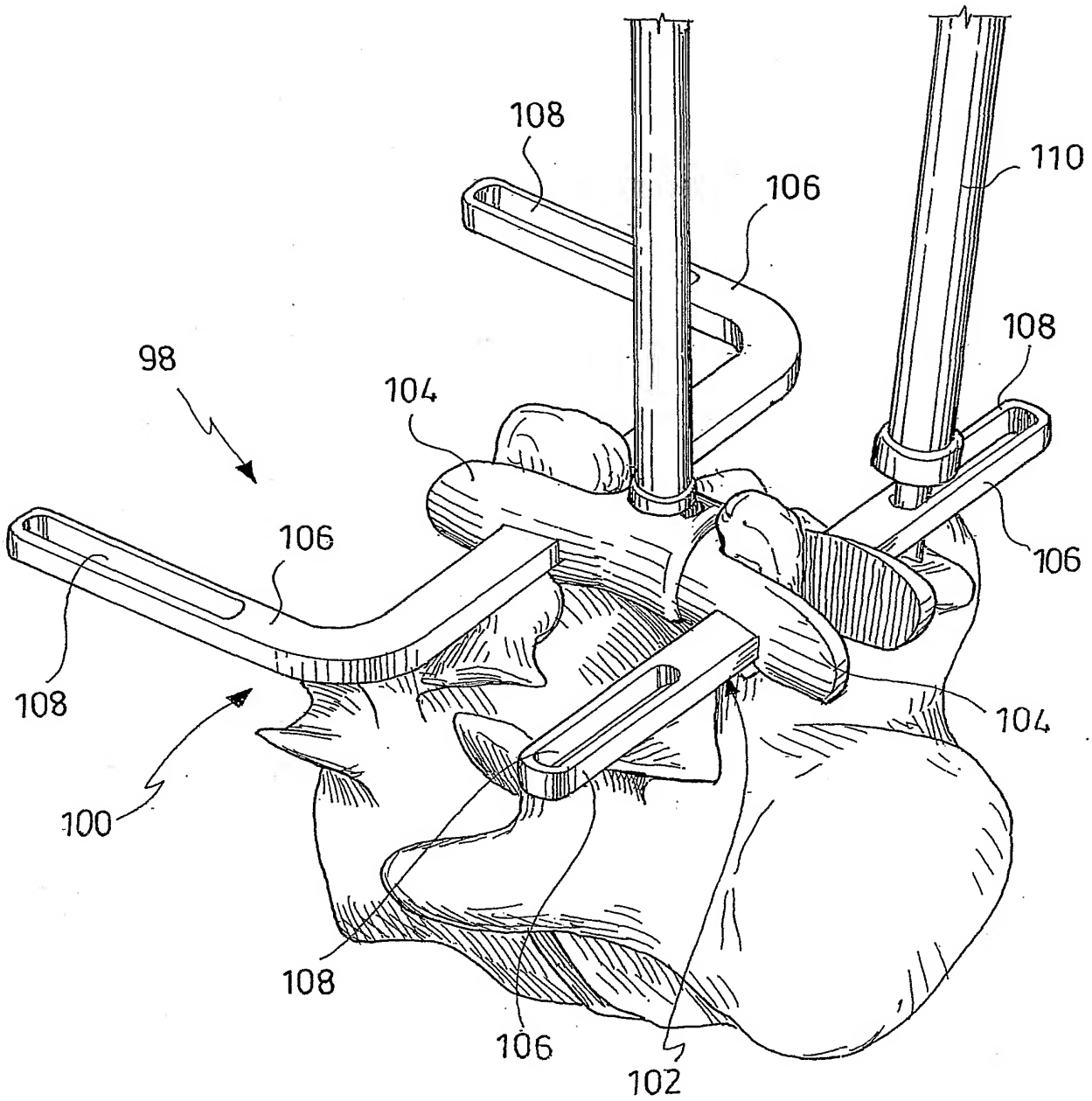


FIG.16

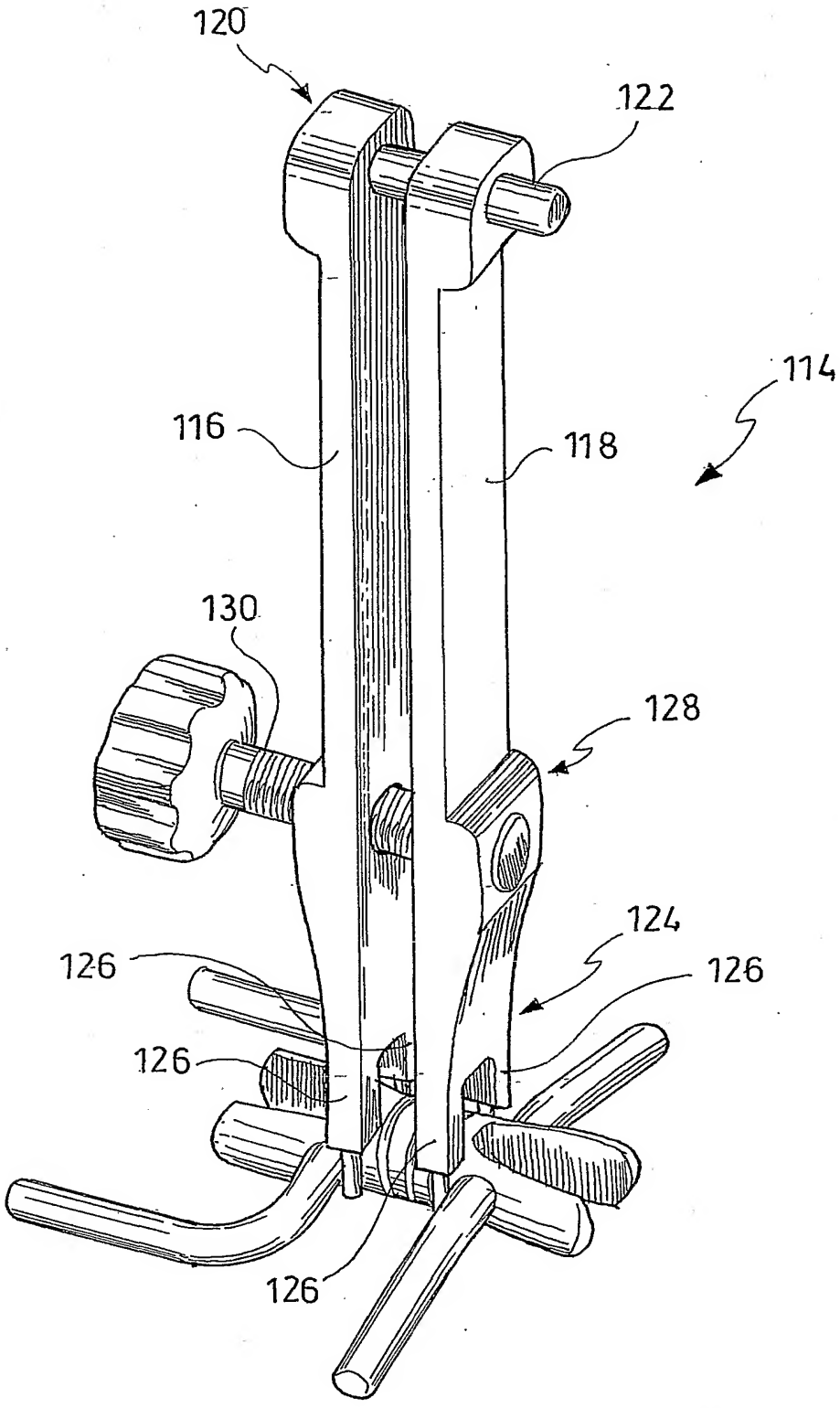


FIG.17A

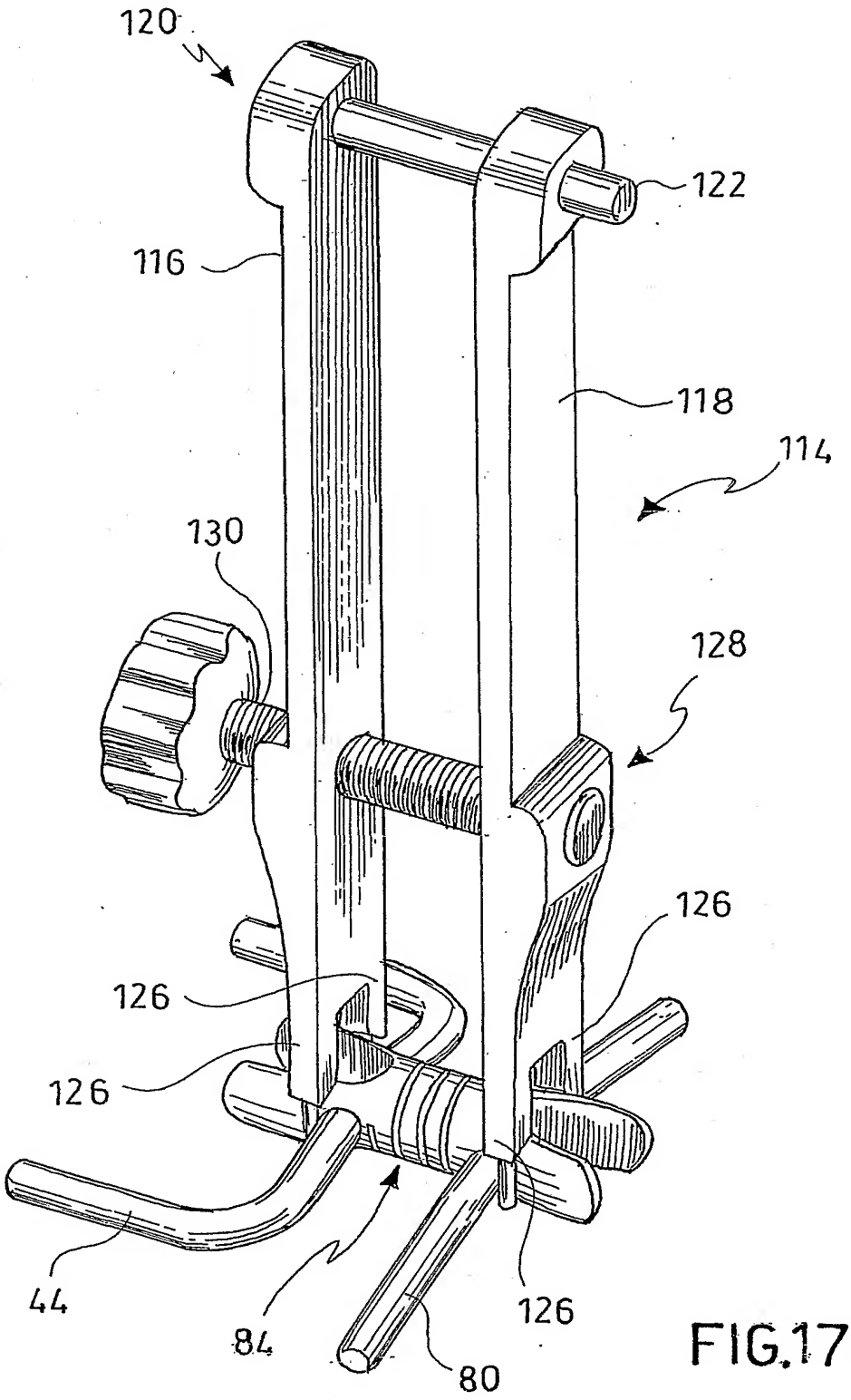


FIG.17B

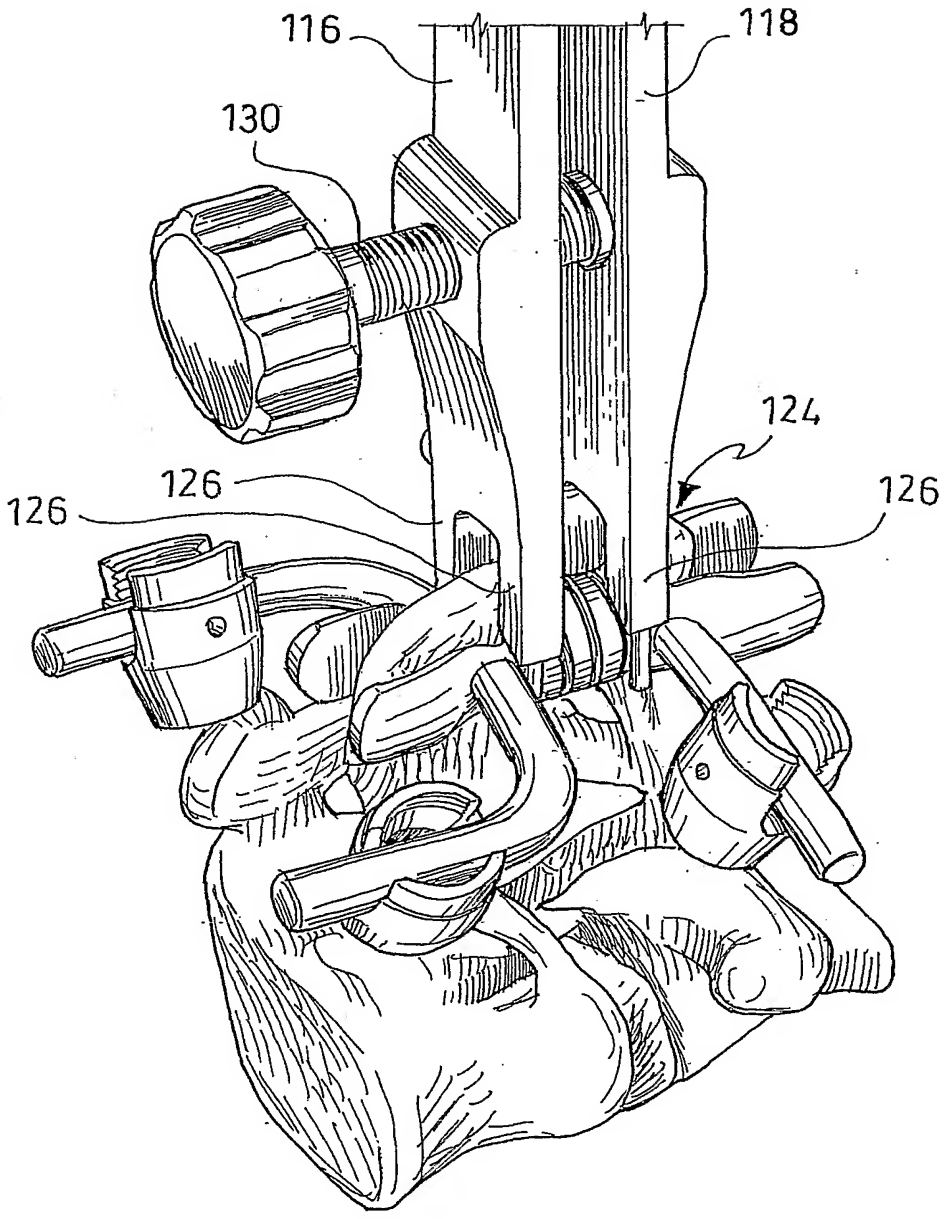


FIG.18

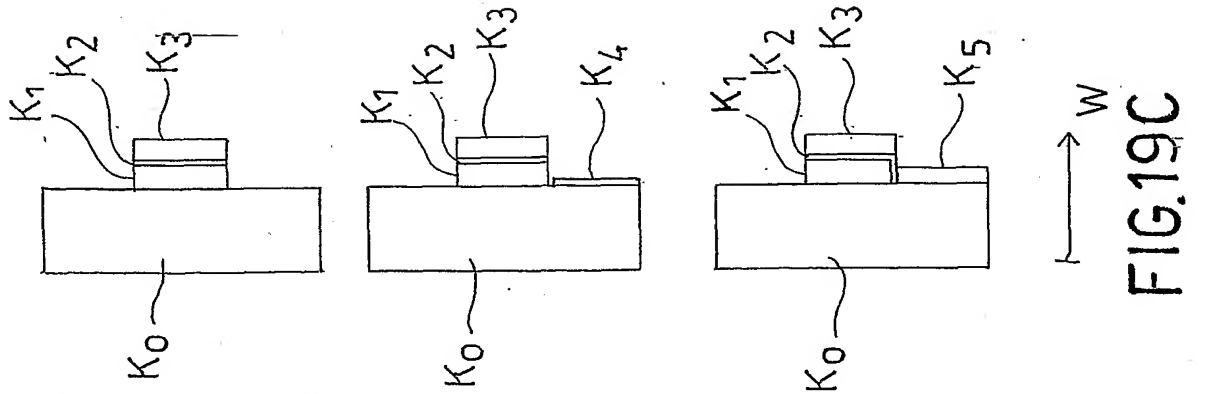


FIG.19C

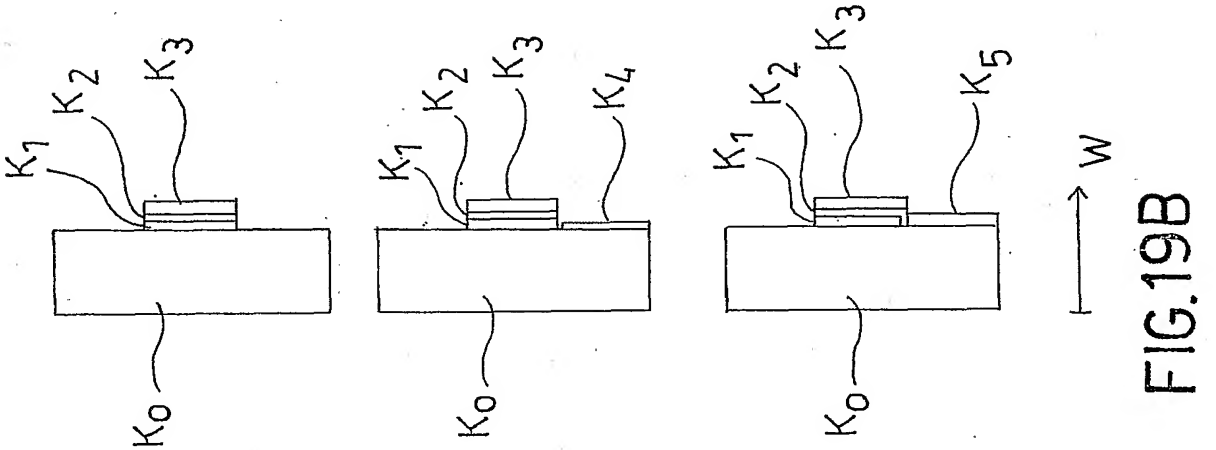


FIG.19B

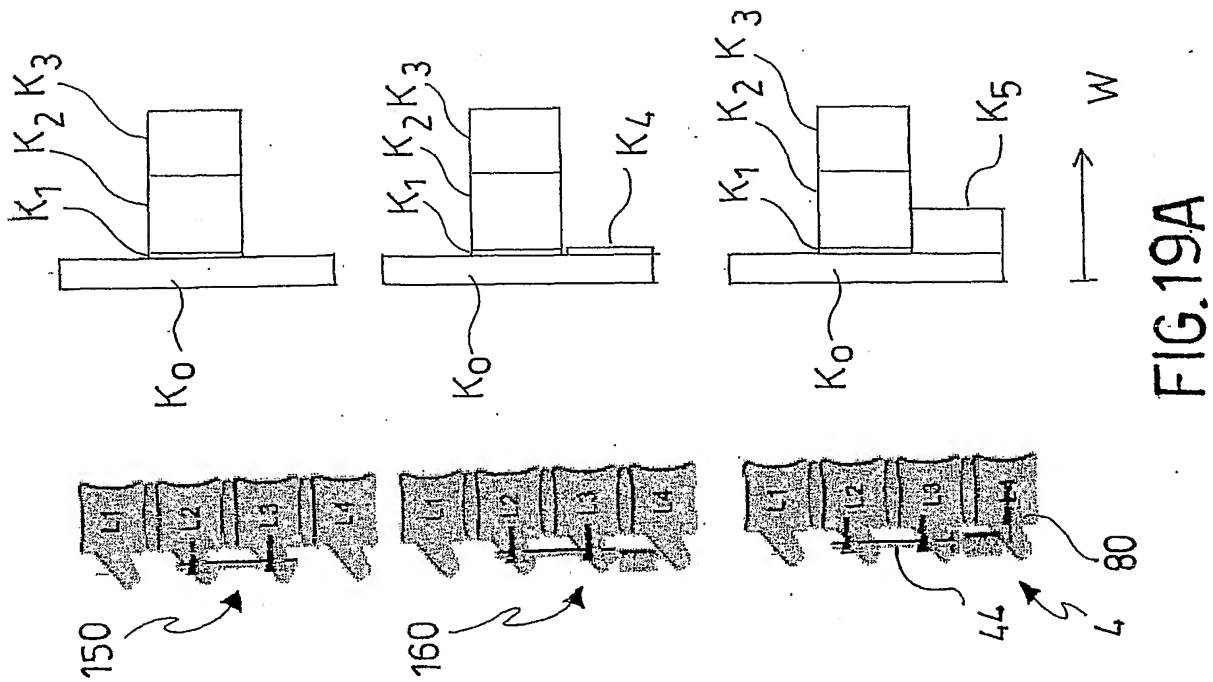


FIG.19A

INTERNATIONAL SEARCH REPORT

PCT/IT2005/000540

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70 A61B17/88

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/102028 A1 (ARNIN URI ET AL) 12 May 2005 (2005-05-12) abstract; figures 7A-8D paragraphs [0038], [0039], [0043]	1-30
A	EP 1 330 987 A (BIOMET MERCK FRANCE; ELBERG, JEAN-FRANCOIS; INDUSTRIAS QUIRURGICAS DE) 30 July 2003 (2003-07-30) abstract; figures 8,9 paragraphs [0039] - [0043]	1
A	US 2003/028250 A1 (REILEY MARK A ET AL) 6 February 2003 (2003-02-06) abstract; figures 18,19	1
A	US 5 733 284 A (MARTIN ET AL) 31 March 1998 (1998-03-31) abstract; figures 1-3,8,11	1,29,30

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 May 2006	08/06/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Macaire, S

INTERNATIONAL SEARCH REPORT

PCT/IT2005/000540

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 440 169 B1 (ELBERG JEAN-FRANCOIS ET AL) 27 August 2002 (2002-08-27) abstract; figures 6-8	18-21

INTERNATIONAL SEARCH REPORT

PCT/IT2005/000540

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 31-34
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/IT2005/000540

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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